NATIONAL INSTITUTE OF SIDDHA

Chennai – 47

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY, CHENNAI – 32

A STUDY ON

GARPA VAAYU

(DISSERTATION SUBJECT)

Submitted by
Dr. S.SHAGILA

For The Partial Fulfillment Of The Requirements to the Degree Of

DOCTOR OF MEDICINE (SIDDHA)

BRANCH I– MARUTHUVAM DEPARTMENT

OCTOBER 2013-2016

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குருவே துணை

கடவுள் வணக்கம்

வேலிருக்குஞ் சரவண சடாட்சரத்துள்

மெய்ப்பொருளுக் கமுதூட்டி வளர்த்த கொங்கைப்

பாலிருக்குங் கௌரிசதா நந்தி சத்தி

பராபரையை சங்கரனைப் பானைத் தண்டை

காலிருக்குங் கடம்பனை சண்முக மயூர் வாழ்

காங்கேயனைக் கதிர்வேலைக் கருத்தில் வைத்து

நூலிருக்கு மாணவர்க்குப் பொறுக்கிச் சேர்த்த

நூலுக்குத் தந்திமுகன் நந்தீசர் காப்பே.

சித்தர்கள் வணக்கம்

நந்தீசர் மூலரகத் தியருஞ் சட்டை

நாதரொடு பதஞ்சலி வியாக்கிரம பாதர்

சுந்தரானந்தர் மச்சமுனி புண்ணாக்கீசர்

கருதிகண்ட கமலமுனி கொங்கணரும் போகர்

மந்திரஞ்சேர் கோரக்கர் சண்டி கேசர்

வரராமர் காலாங்கியார் கூனக் கண்ணர்

தந்திரருஞ்சேர் கருவூரார் ரிஷிகள் தேவர்

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INTRODUCTION

INTRODUCTION

Siddha system of medicine is an integrated part of Indian system of medicine, which is very potent and unique system when compared with other traditional systems in existence. Siddha system clearly lays down the general principles of body constituents in the classic Bootha system. Siddhars hold that the universe is a macrocosm made up of the 5 primordial elements or Boothas, viz Nilam (Earth), Neer (Water), Thee (Fire), Vali (Wind) and Veli (Space) and the human being made up of the same five elements.

"அண்டத்திலுள்ளதே பிண்டம்
பிண்டத்திலுள்ளதே அண்டம்
அண்டமும் பிண்டமும் ஒன்றே
அறிந்துதான் பார்க்கும் போதே"

-சட்டமுனி ஞானம்.

Siddha system is not only deals with medicine but with spirituality, righteous way of living, rejuvenation and means of attains perfection. One who attainment of perfection in life is called as **SIDDHARS**. They had thoroughly studied human body, all kinds of plants, minerals, metals, and poisonous drugs and their physical and chemical properties. They are experts in Alchemy, Yoga, Kayakalpa and the science of Elixir and also in the field of literature, philosophy, astrology etc.

Many chronic diseases considered incurable in western medicine, can be treated successfully in siddha medicine contributing much to the women healthcare. As per saint Agathiyar, One such disease **GARPA VAAYU** mentioned in ***Agathiyar aayulvetham 1200***[(1)]can be correlated to Polycystic ovarian syndrome. The classical siddha literature Agathiyar Ayulvedham 1200 cites that any imbalance in three humors may inhibit the release of ovum from the ovaries. This may be related to the subinfertility due to ovulatory factors.

The symptoms of Garpavaayu are Amenorrhoea, Oligomenorrhoea followed by Menerrhogea, Dysmenorrhoea, Inferility, Missed abortion, Low back ache, Constipation and Obesity. It may be correlated with Poly cystic ovarian syndrome of modern science.

PCOS is a common endocrine disorder of women in reproductive years with prevalence of 5 to 10% childbearing age ranged fom 18 to 40 years and 30% of women have some PCOS symptoms in world wide[(2)]. In India 1 in 40 of Indian adolescent needs hospitalization due to PCOS. Long term hormone replacement therapy for PCOS has been proved unsafe. Since it produces complication such as Deep vein thrombosis, Obesity etc.

Siddhars identified innumerable number of herbs in treating uterine disorders. One such siddha formulation by name **Garpavaayu ilagam** mentioned in ***Aatmarakshamirtham ennum vaithiya saarasangiragam[(3)],*** Which is said to be cost effective, efficasious and simple formulation when compared to other medications.

One of the cause of PCOS is Insulin resistance. The ingridients in Garpavaayu ilagam are said to possesses Anti-diabetic activity, Anti spasmodic activity , Anti obesity activity and Anti hyperlipidemic activity which supports the efficacy of the trial drug and found to possess regulatory agent of menstrual cycle for women with irregular cycles. The above said references and the research works done on the individual ingredients of Garpavaayu ilagam justify its benefit in the treatment of Garpa vaayu (PCOS).

AIM AND OBJECTIVE

AIM:

The evaluate the therapeutic efficacy of siddha formulation "GARPAVAYU ILAGAM"(Internal) in the management of Garpa vaayu (Poly cystic ovarian syndrome).

PRIMARY OBJECTIVE:

To study the Therapeutic efficacy of siddha formulation "GARPAVAYU ILAGAM" (Internal medicine) in the treatment of Garpa vaayu (Poly cystic ovarian syndrome).

SECONDARY OBJECTIVE:

- To prepare the trial drug as per SOP.
- To evaluate the biochemical and physicochemical analysis of the trial drug.
- To study the efficacy of the trial drug through an open clinical trial.
- To study the changes in USG before and after treatment.
- To compare the BMI (Body mass index) before and after treatment.
- To evaluate the infertility ratio among the study patients.

LITERATURE REVIEW

REVIEW OF LITERATURE

SIDDHA ASPECT - GARPA VAAYU

கெர்ப்ப வாயுவின் குணம் : (DEFENITION)

As per Sage Agathiyar, specified Garpa vaayu is characterized by Amenorhea, oligomenorrhoea, Menorrhagia, dysmenorhoea, missed abortion, low back ache, constipation and obesity.

பொருமி ரத்தந்தன்னை மறித்துப் போத மிகவும் வலியுண்டாங்

குருதிசேரா வயிறுவலிபோங் கொள்ளுங் கர்ப்பந்தன்னையழிக்கும்

வருடியிடுப்புக் குடைந்துளைக்கும் மலத்தைமிகவு மிறுக்கிறுக்கி

பெருகப் பணைக்குமெனப் பெரியோர் பேசுங் கர்ப்ப வாயுவிதே.

-அகத்தியர் ஆயுள்வேதம் 1200[2]

கெர்ப்ப ரோகத்தின் குணம்

Yugi muni vaithiya kaviyam specified the symptoms like pain in lower abdomen, generalised body pain and missed abortion under Garpa noigal (Uterine disorder

பொருமித் திரண்டு கீழ்வயிற்றில் புண்பட்டமுந்திச் சீழ்கொண்டு

மருடப்பழகி நின்றக்கால் மயங்கிச் சொல்லேமாறாது

உருவிப்பிழிந்தாற் போல்மேனி உருண்டு உலைந்து ஒடுங்கி

கருவை அழிக்கும் துடியிடையார் கருதும் கெர்ப்பரோகமிதே.

-யூகிமுனி வைத்திய காவியம்(4)

According to Sarabendrar Vaithiya muraikal text the Garpa rogam can be elicit from the symptoms such as pain in lower abdomen, mild fever, head ache and generalised tiredness due to pain.

பொருமி திரண்டு கீழ்வயிற்றில் புண்போலாக மிகநொந்து

முருவக்குத்திக் குடைந்தெங்கும் மொக்கச் சுரமும் தலைவலியும்

வெருவக்குத்திச் செயல் கட்டி வெடித்துப் புண்பட்டோடு பட்டுத்

திருவை பொருத மேனியரே செய்யுமங் கர்ப்ப ரோகமதே.

-சரபேந்திரர் வைதியமுறைகள் கர்ப்பிணி பாலரோக சிகிச்சை[5]

ACCORDING TO T.V. SAMBASIVAM PILLAI AGARATHY

Garpa vaayu is a disease of the uterus attended with flatulence. It is marked by unusual bloody discharge from the vagina, excessive pain, abortion, pain in the loin, heaviness of the abdomen, constipation and other symptoms.

கர்ப்ப நோய்கள் வரும் காரணம் (AETIOLOGY)

Siddha system attributes the etiology of garpa rogam as increase of heat that leads to loss of semen, any kind of infanticide,taking the cow's milk completely without for calf, destroying of young crops

கருதியே கனமான கொடுமை செய்து

கனவனையே நிந்தனைதான் சொன்ன பேரும்

பருதியின் முன்மலசலத் தைவிட்ட பேரும்

பரதேசி யேழைகளைப் பழிக்கின் றோர்க்கும்

குருதியே யிரைக்கின்ற காலந் தன்னில்

கூசாமற் புருஷசங் கைபன்னினோர்க்கும்

சுருதியே பரபோகம் விரும்பி னோர்க்கும்

சுருக்கிலே பெரும்பாடுற் பவிக்குந் தானே.

-யூகி மாமுனிவர் வைத்திய சிந்தாமணி 800[6]

தானென்ற காரங்கள் மிகுக்கை யாலும்

சண்டாளக் கோபத்தின் சலிப்பினாலும்

ஊனென்ற மாமிசங்கள் பொசித்த லாலும்

உறக்கமன்றி விழித்தலா லூழித் தீயால்

பானென்ற பசியின்றிப் பொசிக்கை யாலும்

பாரமாஞ் சுமைதாங்கல் பகலு றக்கம்

கூனென்ற குறுக்கலாய் முடக்கித் தூங்கல்

குரூரமாம் பெரும்பாடு கூடுந் தானே.

-யூகி மாமுனிவர் வைத்திய சிந்தாமணி 800[6]

சுழலாமல் ஸ்திரிகளுக்கு கர்ப்ப நோய் தான்

சூழ்ந்து வந்த காரணத்தைச் சொல்லக் கேளீர்

அழலாலே விந்துவதை அழித்த பாவம்

அஞ்சாமல் பாலகனை கொன்ற பாவம்

குழவியிளம் பிஞ்சு பூப்பறிந்த பாவம்

கோவின் கன்றுக்கின்றி பால்குடித்த பாவம்

விளைவான விளம் பயிரை யழித்த பாவம்

மேதினியில்மடலான விந்தை தானே.

-மாதர் மருத்துவம் (சிதம்பரதாணுப்பிள்ளை)[7]

கெர்ப்ப ரோகம் வகைகள் (CLASSIFICATION)

1. ACCORDING TO YUGIMUNI VAITHIYA KAAVIYAM (14)

Garpa nooigal has been classified into five types. They are,

1.சுரோணித வாய்வு

2.கெர்ப்ப சூலை

3.கெர்ப்ப வாய்வு

4.கெர்ப்ப விப்புருதி

5.இரத்த சூரை வாய்வு

2. ACCORDING TO MEGA NOI, SOOTHAGA NOOL AND ARIVAIYAR CHINTHAMANI (15)

Garpa noigal is classified into six types .

1.கெர்ப்ப வாயு

2.கெர்ப்ப சூலை வலி

3.சல சூலை

4.இரத்த சூலை

5.சூதக வாயு

6.விப்புருதி வாயு

3.ACCORDING TO AGASTHIYAR AAYULVEDHAM – 1200 (2)

Following types of Garpa noigal are described in Agasthiyar Aayulvedham

1.கெர்ப்ப வாயு

2.கர்ப்ப விப்புருதி

3.கர்ப்ப சூலை

4.இரத்த சூலை

5.சூதக வாயு (சூசிக வாயு)

CLINICAL FEATURES OF GARPA VAAYU

A. ACCORDING TO YUGIMUNI VAITHIYA KAAVYAM [4]

பொருமி ரத்தந்தன்னைச் சொரியும் போத மிகவும் வலியுண்டாம்

குருதிக்கழியில்வலிஅமரும் கொள்ளும் கர்ப்பந்தன்னையழிக்கும்

கருகிஇடுப்பும் கடுத்துளையும் கனத்தேவயிறுமலம்கட்டும்

பெருகப் பணைக்கும் தனத்தினர்க்கும் பேசுங் கெர்ப்ப வாயுவிதே.

Menorrhagia, dysmenorrhoea, pain subside when the menstrual flow increases, missed abortion, low back ache, obesity are the features of Garpa vaayu

B. ACCORDING TO MEGA NOI, SOOTHAGA NOOL AND ARIVAIYAR CHINTHAMANI

வாறான கெர்ப்ப வாயு வகையே தென்றால்

வளர் மாதவிடை காலம் வயிற்றில் நோயாம்

கூறான சுரோணிதம் தான் இறைச்சி நீர் போல்

கூன்ற சரத்தில் இடைவிட்டு முழுக்குண்டாகும்

பேறான புருஷனுடன் கூடும் காலம்

பெரு மிறைச்சி நீரது போல் துணியில் காணும்

வீறாக தேகமது வெளுத்து போகும்

விளங்கு திணப்பதிக மதாயுண்டாங் காணே.

-மேகநோய், சூதகநூல் மற்றும் அரிவையர் சிந்தாமணி[8]

The following symptoms like discomfort in abdomen during menstruaton, passing big clots during menstruation, irregular menstruation and anaemia are present in garpa vaayu .

D. ACCORDING TO PARARASASEKARAM [9]

திருவனையா ருதரமதிற் கெர்ப்ப ரோகஞ்

செப்பினரொன் பதுபேதஞ் செய்ய சோரி

மருவுசுரஞ் சூலைமிகு வாயு மேலும்

வருத்துபுழு விற்புருதி வன்புணர்ச்சி

கருவிலுறு வஞ்சனையு மருந்தி னீடும்

கழறினரிங் கிவற்றுளைந்தும் தீரு மென்று

பொருவரிய தமிழ்முனிவ னன்று ரைத்த

பொருளாராய்ந் தறிதல்கடன் புலமை யோர்க்கே.

According to Pararasasekaram, Garpa vaayu is one among the nine types of Garpa noigal. They are as follow

1.சுரோணித கெர்ப்ப வாயு

2.சுரத்தின் மேல் கெர்ப்ப ரோகம்

3.கெர்ப்ப சூலை

4.கெர்ப்ப வாயு

5.கெர்ப்ப கிருமி

6.கெர்ப்ப விப்புருதி

7.கெர்ப்ப புணர்ச்சி

8.கெர்ப்ப வஞ்சனை

9.கெர்ப்ப மருந்தீடு

கெர்ப்ப வாயுவின் குணம்

பொருமு முதரந் தனையடர்த்துப் போத மிகவும் வலியுண்டாய்க்

குருஹிகழியில் வலிதீருங் கொள்ளுங் கெர்ப்ப முறவழிக்கும்

வருடி யிடுப்புத் துடையுளையு மயக்கு மலத்தை மிகவிறுக்

பெருகப் பணைக்கும் முதரத்திற் பேசும் கெர்ப்ப வாயுவிதே.

வேராமிடது பாகத்தின் மிண்டி வலிக்கு மேலேறும்

சாருங் குருதி தணியாது தலையாமெனவே தலை திமிர்க்கும்

நேரே திரளு நாபிக்கீழ் நிர்க்குஞ் சாய்கை யதிற்சாரும்

நாரி கடுக்குஞ் சந்துளையு நலஞ்சே ருதரந் தனில்வலியே

Amenorrhoea, oligomenorrhoea followed by menorrhagia, dysmenorrhoea subsides as the flow increases, severe pain in low back region and in thigh, giddiness, constipation and obesity.

சுரத்தின் மேல் கெர்ப்ப ரோகம்

நீறுஞ் சுரமா யுடம்புலரு நீருஞ் சிவக்கு மடிவயிற்றில்

ஊறு மிகவே கறைபடும்போ துடனே நீரு மொடுவாகும்

தேறுங் கருவை யழிப்பிக்குந் தினமே காந்தன் மிகும் பொருமும்

கூறுஞ் சோரி யிலதாகுங் கொடிய சுரத்தின் குணமாமே.

Dryness of skin, hematuria, lower abdominal pain, menorrhagia, abortion are the features of above disease.

சுரோணித கெர்ப்ப வாயு

திரண்டு புரண்டு கீழ்வயிற்றில் திதமாய் மாதவிடாய் போலும்

மருண்டு குருதி மிகுந்துவரும் வாய்நீர் பெருத்து மயங்கி வரும்

அருண்டு சிலநாள் விரத்த ரோகமென வுறுதி யதுகண் டுணர்வீரே.

உந்திக்கீ முதரம் புக்கி யுலமென விருக்கு மோடிச்

சந்துகள் விருவி ருத்துத் தானுடல் நடுங்கி யெங்கும்

மந்தமா யுடம்பு ழற்றி மறுகியுட் சத்தி தோன்றில்

இந்தமா குணங்கள் கண்டா லிதுகெர்ப்ப சுரோணி யென்றே.

Lower abdominal discomfort followed by excessive bleeding like menstruation, excessive salivation, giddiness, lower abdominal pain ,abortion , numbness in joints, nausea, giddiness, generalised body pain and prostration.

கெர்ப்ப சூலை

திரண்டுகீழ் வயிற்றிற் றோன்றிச் சிக்கிநின் றிரத்தம் வீழ்ந்து

பிரண்டுதானுதர மெங்கும் பிள்ளைபோ லாகவூரும்

அருண்டுதானழுக்க தானாலதனுடன் வலியுந் தோன்றும்

உருண்டிடுங் கெர்ப்ப சூலந் தானென வுரைக்கலாமே

திரண்டுகீழ் வயிற்றைப் பற்றிச் சிக்கிநின் றிரத்தம் வீழ்ந்து

புரண்டுதான் வலிக்கு மாகிற் பொல்லாத கெர்ப்ப சூலை

வரண்டுமே வெளுத்து வற்றி மயங்கிடக் குருதி சோரில்

உருண்டிடா விரத்த ரோக முறுதியா யுரைக்கலாமே

Excessive painful bleeding during menstruation, abdominal distention as in pregnancy, anaemia.

கெர்ப்ப கிருமி

பொருமித் திரண்டு கீழ்வயிற்றிற் புண்பட்டழுந்திச் செயல்கொண்டு

மருவி வலிக்கும் வெள்ளையுண்டாம் வாய்நீ ருறு முவாந்திக்கும்

உருவிப் பிழிந்தாற் பொன்மேனி யுலர்ந்து தியங்கு மொடுவுண்டாம்

கிருமித் தோஷ மதுவென்னுங் கெர்ப்ப ரோகக் குணமாமே.

Severe abdominal pain , whitish discharge, nausea, vomiting and dryness of skin are present in Garpa kirumi.

கெர்ப்ப விப்புருதி

அடிவயி றதைத்து விம்மியழுந்திடும் பண்போ னோவாம்

தடைஅட விரத்த நின்று சற்றுச்சற் றாக வீழும்

இருடற வலிக்கு மாத விடையினா லிரத்த மில்லை

மிடைபடுங் குணமே கெர்ப்ப விற்புருதி யென்னலாமே.

வயிற்றை வலிக்கும் வெள்ளெச்ச மதுபோற் பிடவை தனிற்படுமாம்

உயிர்ப்பைச் சிறந்த வுடலுருக்கு முவந்தன் னத்தி னாடாது

வெயிற்கட் பொறாது தாகமுமா மிகவே மேனி தளர்ச்சியுண்டாம்

குயிற்சொற் பயிலுங் கொடியிடையீர் குறிக்கும் விற்புரு திக்குணமே

Distention of abdomen due to tumour, pain in abdomen, irregular menstruation followed by oliguria, dysmenorrhea, whitish discharge, loss of appetite, thirst and generalised tiredness

கெர்ப்ப புணர்ச்சி

இந்திரி யந்நீர் போல விடைவிடா தொழுகி வீழும்

உந்தவே தங்குங் கெர்ப்ப முடைபடு முதிர மாகச்

சிந்தியே யோடும் வாயு திரட்சியாய்ச் செறுத்து விம்மும்

புந்தியை மயக்குங் கெர்ப்பப் புணர்ச்சியின் குணமா மென்னே.

Excessive vaginal discharge following intercourse and missed abortion .

கெர்ப்ப வஞ்சனை

பஞ்சென வெளுக்கு மேனி பறிந்திடுந் தலையு ரோமம்

நெஞ்சுற வெரித்து வாய்நீ ரூறியே நிதம்பங் காய்ந்து

மிஞ்சவே கோரை சாயும் வேர்வையு மிகவுண்டாம்

வஞ்சனைக் குறையாங் கெர்ப்பம் வருத்திடுங் குணங்கடாமே.

Anemia, loss of hair, burning sensation in chest, excessive body heat followed by menorrhagia, hyperhidrosis

கெர்ப்ப மருந்தீடு

அருந்திடும் பொசிப்புக் காணாவரவுலர்ந் தத்தி யாகும்

வருந்தியே நெஞ்சு லர்ந்து வறட்சியா யிரும லுண்டாம்

பொருந்தியே கெர்ப்ப நீர்போற் பொங்கியே யுதிரம் போகா

மருந்தினீ டதனால் வந்த கெர்ப்பநோய் வகையி தாமே

Loss of appetite, chest discomfort followed by dry cough, amenorrhoea are the symptoms in maruntheedu Garpa noi.

ACCORDING TO PARARASASEKARAM [9]

Of the 9 types of Garpa noigal five are curable and four are incurable i.e., it can be treated only after long term treatment

வஞ்சிக் கொடியா ருத்ரமதின் மருவுங் கெர்ப்ப ரோகமது

மிஞ்சுஞ் சுரோணி சுரஞ்சூரை மிகுந்த வாயு கிருமியொடு

செஞ்சொன் மடவவீர் விற்புருதி சேரும் புணர்ச்சி வஞ்சனையோ

டொஞ்சு மருத்தி டொன்பதினா லுறுமே கெர்ப்ப ரோகமதே.

இரத்த ரோக மத்திசுரத் தெடுத்த நோவு சூலையினம்

உரத்த வாயுத் திரட்சியோ டுறையுங் கிருமி விற்புருதி

வருந்தும் புணர்ச்சி வஞ்சனையு மருந்தினீடு மொன்பதனுள்

திருத்த மாக முன்னான்குந் தீரா தைந்துந் தீருமன்றே.

சாத்திய வகைகள்

1. கெர்ப்ப விப்புருதி
2. கெர்ப்ப புணர்ச்சி
3. கெர்ப்ப வஞ்சனை
4. கெர்ப்ப மருந்தீடு

அசாத்திய வகைகள்

1. சுரோணித கெர்ப்ப வாயு
2. சுரத்தின் மேல் கெர்ப்ப ரோகம்
3. கெர்ப்ப சூலை
4. கெர்ப்ப வாயு
5. கெர்ப்ப கிருமி

முக்குற்ற வேறுபாடுகள் (Pathology)

In Siddha system the manifestations of all diseases are due to the derangement of tridoshas i.e., vaatham, pitham and kabam.

நோய் கணிப்பு முறை

In piniyari muraimaigal following principles are followed in Siddha system. They are

- Poriyaaltherithal - Inspection
- Pulanaal arithal - Palpation
- Vinaathal - Interrogation

Poriyaaltherithal - Porigal is the five sense organs of perception namely Nose, Tongue, Eye, Skin and Ear.

Pulanaal arithal – Pulangal is the five senses namely smell, sound, taste, sight sensation. Physicians use their pori and pulan to examine the pori and pulan of the patient respectively.

Vinathal – Getting informations about the history of the diseases from the patient or from the attenders of him, when the patient is not in a position to speak or if the patient is a child.

ENVAGAI THERVUGAL:

“நாடி ஸ்பரிசம் நாநிறம்மொழி விழி மலம் மூத்திரம்

இவையனைத்தும் மருத்துவன் ஆயுதம்”[10].

1) **Naadi:** The three Uyirthaathukkal are formed by the combination of

Edakalai + Abanan = Vatham

Pinkalai + Piranan = Pitham

Suzhumunai + Samanan = Kabam

In Garpa vaayu Vatha naadi or Vatha thontha naadigal were seen commonly

மாதர் கைப்பிடித்த போது வந்திடும் வாதநாடி

தீதறுவெடித்து பாய்ந்து சிதறியே சிலம்பிநின்றாற்
பேதைதன்வயிற்றின் உள்ளே பெருகு சுரோணிதமே தங்கி
வாதைகள் பண்ண மாதவிடைகாலம் வருத்தம் செய்யும்
இடுப்பொடு கடுத்து நொந்து இடைவிடாக் குத்தலுண்டாய்
தடுத்திடா கர்ப்பந்தனை தங்கிடா வண்னம் செய்யும்.

-பதிணெண் சித்தர்கள் நாடி சாஸ்திரம்

The deranged Vatha naadi produces painful menstruation, excessive bleeding and generalised body pain. Finally it leads to infertility.

வாதநாடி

வாதமெனும் நாடியது தோன்றில்
சீதமந்தமொடு வயிறுபொருமல் திரட்சிவாயு
சீதமுறுங் கிராணி மகோதரம் நீராமை
திரள்வாயு சூலை வலிக்கடுப்புத் தீரை
நீதமுறுங் கிருமிகுன்மம் அண்ட வாதம்
நிலையும் நீர்க் கிரிச்சரங்கள் தந்து மேகம்
பேதகமாமுதரப் பிணி மூலரோகம்

பேசவெகு பிணிகளுமே பொருள தாமே.

வாதபித்த தொந்தம்

பொருளான வாதத்தில் பித்தஞ் சேர்ந்து

பொருந்து குணங்களா முஷ்ணவாயு சத்தி

செரியாமை புளித்தேப்பம் பொருமல் நீரிற்

சிவப்புமலம் பிடித்தலுருந் தாதுநட்டம்

கருவான தேகமதிலுளைச்சல் சோம்பல்

கைகால் தறிப்புநாக் கசக்கு மன்னம்

பரிவான ஊண்குறைதல் ருசிகேடாதல்

பலநோயும் வருத்திவைக்கும் பாங்கு தானே.

கபவாத தொந்தம்

கண்டாயொ சிலேற்பனத்தில் வாத நாடி

கலந்திடுகில் வயிறு பொருமல் கனத்த வீக்கம்

உண்டாலோ ஓங்காரஞ் சத்தி விக்கல்

உறுதிராட்சை வாய்வுவலி சந்நி தோடம்

விண்டாலே இளைப்பிருமல் சோபை பாண்டு

விடபாகம் விடசூலை பக்கவாதம்

திண்டாடு நாசிகாபீடங் கக்கல்

சிரநோய்கள் பலவும்வந்து சிக்குந் தானே.

-சதகநாடி [10]

2) **Sparisam:** Tenderness over lower abdomen and mild increase in temperature.

3) **Naa:** Coated, pallor and dryness.

4) **Niram:** Depending on the body constitution it may be black, yellow, whitish or mixed colour.

5) **Mozhi:** Normal vocal resonance present.

6) **Vizhi**: Conjunctival pallor present.

7) **Malam:** May have constipation

8) **Moothiram:**

Neerkuri: The colour of Urine is straw colour in general and in some cases it was noted to beyellow.

Neikuri: Patients were advised to collect the early morning urine in a glass container and is subjected to analysis without disturbing its nature and the neikuri should be noticed in direct sunlight within 3 hours. Neikuri shows the following shapes

"அரவெண நீண்டில் அ தே வாதம்

ஆழிபோல் பரவில் அ தே பித்தம்

முத்தொத்து நிற்கில் மொழிவதன் கபமே"*(10)*.

When the oil drops lengthens like a snake it indicates 'Vatha Neer'

When the oil drops spreads like a ring it indicates 'Pitha Neer'

When the oil drops remains that of pearl it indicates 'Kaba Neer'

MANAGEMENT

மிகுனும் குறையினும் நோய் செய்யும் நூலோர்

வளிமுதலா யெண்ணிய மூன்று.

According to siddha system the main aim of treatment is the removal of udarpini and manapini by correcting the deranged doshas.

NEEKKAM

Treatment is not only aimed at removal of disease, but also for preventing the disease and improving the immunity.

The three humours which are responsible for organization, regulation and integration of the bodily structures and functions are always kept in a state of equilibrium by word, thought, deed, and food. The imbalanced doshas are balanced by administering internal medicine or emetic or eye application and also through appropriate systemic therapy. The general aetiological factors are said to be caused by changes in life style and stress. So it is essential to know the disease and the cause for the onset of disease, the nature of the patient, the severity of illness and the time of occurrence of the diseases must be observed.

The line of treatment is to bring down the deranged mukkutram by giving purgative which normalise the deranged vatham which is one of the cause for garpa vaayu, then treated with suitable medicine indicated in ancient siddha literature with proper diet regimen

"விரேசனத்தால் வாதந்தாழும்

வாந்தியால் பித்தம் தாழும்

அஞ்சனத்தால் கபம் தாழும்"

-சித்த மருத்துவாங்க சுருக்கம்

According to the siddha text medicines should be given to induce purgation before starting the treatment to bring the deranged doshas to normal.

பத்தியம்

பத்தியத்தினாலே பலன் உண்டாகும் மருந்து

பத்தியங்கள் போனால் பலன்போகும் - பத்தியத்தில்

பத்தியமே வெற்றிதரும் பண்டிதர்க்கு - ஆதலினால்

பத்தியமே உத்தியென்று பார்

-தேரையர் வெண்பா

DIET AND ADVICE:

- Plenty of Green vegetables, water, Goose berry, Fish, Sprouted black gram, Butter milk, Fig fruit, Honey, Tender brinjal, Bananna, Pome granate regularly.
- Patients were advised to avoid Bitter gourd, Mango, sesban, Chicken, Meat, Chocolate, Horse gram, Ghee, Tamarind Packaged food, Fatty food stuffs Sweetened beverages, Preserved cool drinks, Baked food items, Oily food items, green plantain etc.,
- Advise yogasanas like Sarvaangasana, Matsyaasana, Shirasasana, Shavasana, Haalasana, Patchimottaanaasana, Dhanurasana and Naadi shuddhi. All these asanas stimulate internal organs, endocrine glands governing menstruation.

ANATOMY AND PHYSIOLOGY OF FEMALE REPRODUCTIVE SYSTEM

INTRODUCTION

All living things reproduce. Reproduction is the process by which organisms make more organisms like themselves. It is one of the things that sets living things apart from non-living matter. But even though the reproductive system is essential to keeping a species alive, unlike other body systems, it's not essential to keeping an individual alive.

FEMALE REPRODUCTIVE SYSTEM

The female reproductive system includes the ovaries, fallopian tubes, uterus, vagina, vulva, mammary glands and breasts. These organs are involved in

- Production and transportation of gametes
- Secretes sex hormones
- Facilitates the fertilization of ova by sperm
- Protects and nourishes the fertilized egg until it is fully developed
- Delivers fetus through birth canal
- Provides nourishment to the baby through milk secreted by mammary glands in the breast

Internal Genitals

Ovaries

The **ovaries** are a pair of small glands about the size and shape of almonds, located on the left and right sides of the pelvic body cavity lateral to the superior portion of the uterus. Ovaries produce female sex hormones such as oestrogen and progesterone as well as ova (commonly called "eggs"), the female gametes. Ova are produced from oocyte cells that slowly develop throughout a woman's early life and reach maturity after puberty. Each month during ovulation, a mature ovum is released. The ovum travels from the ovary to the fallopian tube, where it may be fertilized before reaching the uterus.

Fallopian tubes

The **fallopian tubes** are a pair of muscular tubes that extend from the upper corners of the uterus to the edge of the ovaries. The fallopian tubes end in a funnel-shaped structure called the infundibulum, which is covered with small finger-like projections called fimbriae. The fimbriae lies close to the ovary, but is not attached. The ovaries alternately release an egg. When an ovary does ovulate, or release an egg, it is swept into the lumen of the fallopian tube by the fimbriae if enough sperm are ejaculated during inter course fertilization will occur. The tiny hairs in the tube's lining help push it down the narrow passageway towards the uterus.

Uterus

The **uterus** is a hollow, muscular, pear-shaped organ located near the floor of pelvic cavity. Connected to the two fallopian tubes on its superior end and to the vagina (via the cervix) on its inferior end, the uterus is also known as the womb, as it surrounds and supports the developing foetus during pregnancy. The inner lining of the uterus, known as the endometrium, provides support to the embryo during early development or it is sloughed off during menses. The visceral muscles of the uterus contract during childbirth to push the foetus through the birth canal. These muscles also contract rhythmically during an orgasm in a wave like action. It is thought that this is to help push or guide the sperm up the uterus to the fallopian tubes where fertilization may be possible.

Vagina

The vagina is a fibro muscular tube that extends from the vaginal opening to the cervix. It is located between the urinary bladder and the rectum. The vagina is made up of three layers, an inner mucosal layer, a middle muscular layer, and an outer fibrous layer.

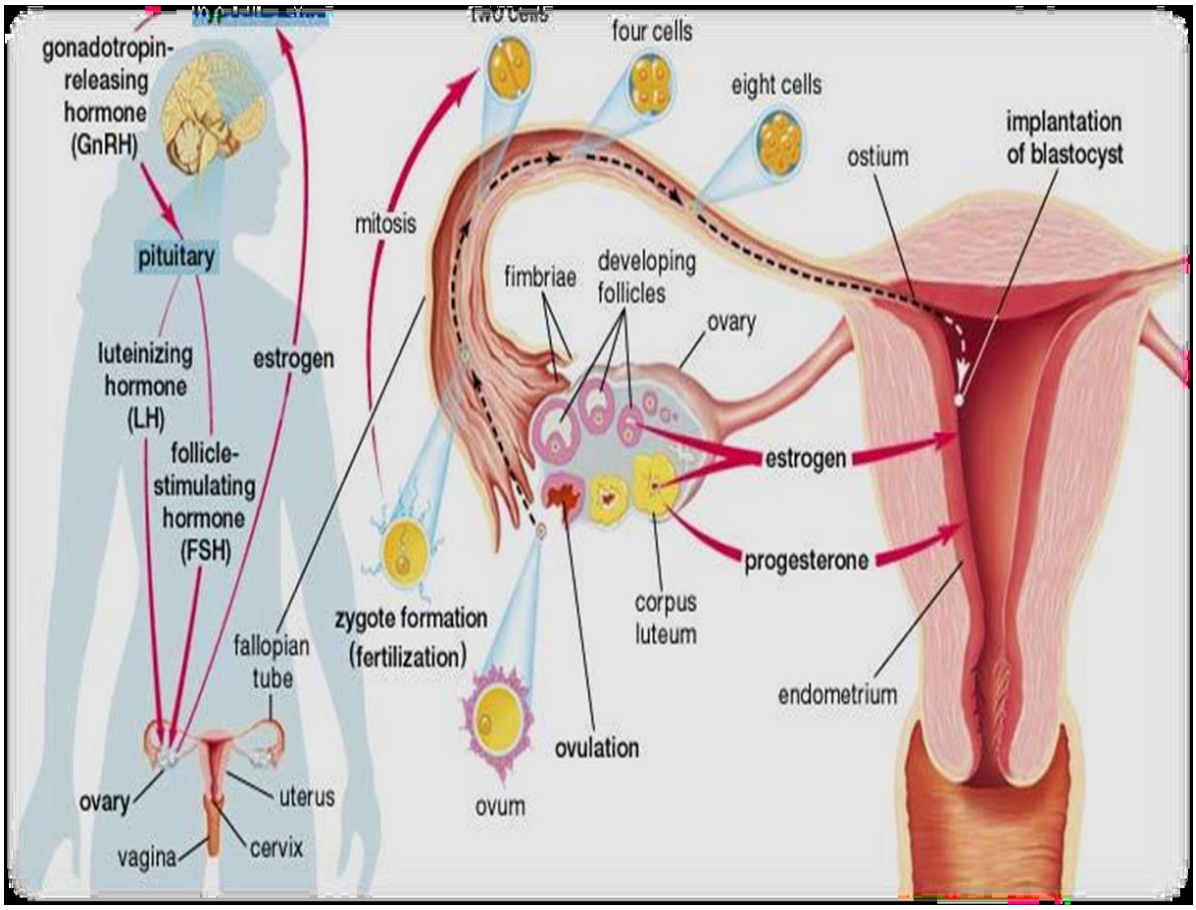
Functions of the Vagina

- Receptacle for the penis during sexual intercourse
- Pathway for delivery of the foetus during child birth
- Provides the route for the menstrual flow from the uterus, to exit the body.
- May hold forms of birth control, such as a diaphragm, FemCap, Nuva Ring, or female condom.

Cervix

The cervix is the lower, narrow portion of the uterus where it joins with the top end of the vagina. It is cylindrical or conical in shape and protrudes through the upper anterior vaginal wall. Approximately half its length is visible with appropriate medical equipment; the retainder lies above the vagina byond view. It is occasionally called “cervix uteri”, or “ neck of the uterus”. The portion projecting into the vagina s referred to as the portio vaginalis or ectocervix. The ectocervix’s opening is called theexternal os. In women who have not had a vaginal birth the external os appears as a small circular opening. The passageway between the external os and the uterine cavity is referred to as the endocervical canal. The endocervical canal terminates at the internal os which is the opening of the cervix inside the uterine cavity.

ANATOMICAL REPRESENTATION OF UTERUS



Vulva

The vulva is the collective name for the external female genitalia includes the **mons pubis** (a fatty mound which covers the **pubic bone),** the **labia majora** (outer lips of the vagina), the **labia minora** (the inner lips of the vagina), the **vaginal opening,** the **urethral opening** (opening of the **urethra,** a tube which carries urine from the bladder outside of the body), the **clitoris** (a small structure with sensitive nerve endings located within the labia minora, the sole purpose of which is for sexual arousal and pleasure), and the **perineum** (the space between the **anus** (the rectal opening) and the vaginal opening)

Breasts and Mammary Glands

The breasts are specialized organs of the female body that contain mammary glands, milk ducts, and adipose tissue. The two breasts are located on the left and right sides of the thoracic region of the body. In the center of each breast is a highly pigmented nipple that releases milk when stimulated. The areola, a thickened, highly pigmented band of skin that surrounds the nipple, protects the underlying tissues during breastfeeding. Mammary glands are enlarged and modified sweat glands. Within each breast , 15 to 20 clusters of mammary glands become active during pregnancy and remain active until milk is no longer needed. The milk passes through milkducts on its way to the nipple, where it exist the body.

HORMONES THAT CONTROL THE REPRODUCTIVE CYCLE

Five hormones play important role in the reproductive cycle. Of these three are produced in the brain and the other two are made in the ovaries.

- **Gonadotrophin-releasing hormone (GnRH)** is secreted by the hypothalamus. It controls the release of Follicle-stimulating hormone (FSH) and Luteinizing hormone (LH).

- **Follicle-stimulating hormone** (**FSH)** is released by the anterior pituitary. FSH is carried by the blood stream to the ovaries. Here it stimulates the immature ova to start growing.

- **Luteinizing hormone** (**LH)** is also released by the anterior pituitary and travels to the ovaries. LH triggers ovulation and encourages the formation of a special group of cells called the corpus luteum.

- **Oestrogen** is produced by the growing ova and by the corpus luteum. In moderate amounts oestrogen helps to control the levels of GnRH, FSH and

LH. This helps to prevent the development of too many ova. Oestrogen also helps to develop and maintain many of the female reproductive structures.

- **Progesterone** is mainly released by the corpus luteum. It works with oestrogen to prepare the lining of the uterus for the implantation of a fertilised ovum. It also helps to prepare the breasts for releasing milk. High levels of progesterone control the levels of GnRH, FSH and LH.

FEMALE REPRODUCTIVE CYCLE

The female reproductive cycle is the process of producing an ovum and readying the uterus to receive a fertilized ovum to begin pregnancy. Approximately every 28 days , during ovulation an ovary sends egg into one of the fallopian tubes. Unless the egg is fertilized by a sperm in the fallopian tube within two to three days following ovulation, the egg dries up and leaves the body about two weeks later through the vagina. This process is called menstruation.

Blood and tissues from the inner lining of the uterus (the endometrium) combine to form the menstrual flow, which generally lasts for four to seven days. During menstruation arteries that supply the lining of the uterus constrict and capillaries weaken. Blood spilling from the damaged vessels detaches layers of the lining, not all at once but in random patches. Endometrium mucus and blood descending from the uterus, through the liquid creates the menstruation flow.

The Menstrual Cycle/ reproductive cycle can be divided into an ovarian cycle and a uterine cycle.

UTERINE CYCLE

The uterine cycle operates in synchronize with the ovarian cycle and is divided into three phases.

Menstrual phase:

It is named the menstrual phase because it corresponds with the shedding of the uterine lining. The corpus luteum degenerates causing plasma estrogen and progesterone levels to come down and in turn causes menstruation. Blood vessels in the outer most layer of the endometrium constrict and decrease blood flow to the tissues lead necrosis. After the tissues die they start to separate from the underlying endometrial tissues. Eventually the dead tissue is shed. This shedding of the tissues ruptures blood vessels and causes bleeding.

Proliferative phase:

During this phase the uterus renews itself and prepares for pregnancy. It last until the 14th day of a 28 days cycle. It is also referred as oestrogenic phase. The endometrial tissue that is left after menstruation begins to grow. The endometrial glands grow and enlarge causing more blood vessels. The cervical canal has glands that secrete a thin mucous that helps deposited sperm. Estrogen promotes uterine changes in this phase.

Secretory phase:

The secretory phase of endometrium begins on the 15th day and persists until the onset of menstruation. In this the endometrium is transformed to make it the best environment for implantation and subsequent housing and nourishment of the developing embryo. By doing this the endometrium will have an enriched blood supply, begin to secrete fluids rich in glycogen, and even form a plug at the end of the cervical canal so that microorganisms cannot enter. These changes in the uterus caused by progesterone, due to the corpus luteum. At the end of the secretory phase the corpus luteum degenerates and progesterone levels fall. This will trigger menstruation.

OVARIAN CYCLE

The Follicular Phase

Several follicles commence to develop in each menstrual cycle. Of these several follicles, one follicle grows faster than the rest and produces more FSH receptors and estrogen. The rising estrogen level stimulates LH receptor in the theca cell but causes a negative feedback to the anterior pituitary gland leading to a progressive fall in level of FSH and gonadotropic support to the other lesser developed follicle which atrophy. The dominant follicle develops into graffian follicle results in ovulation.

Ovulation phase

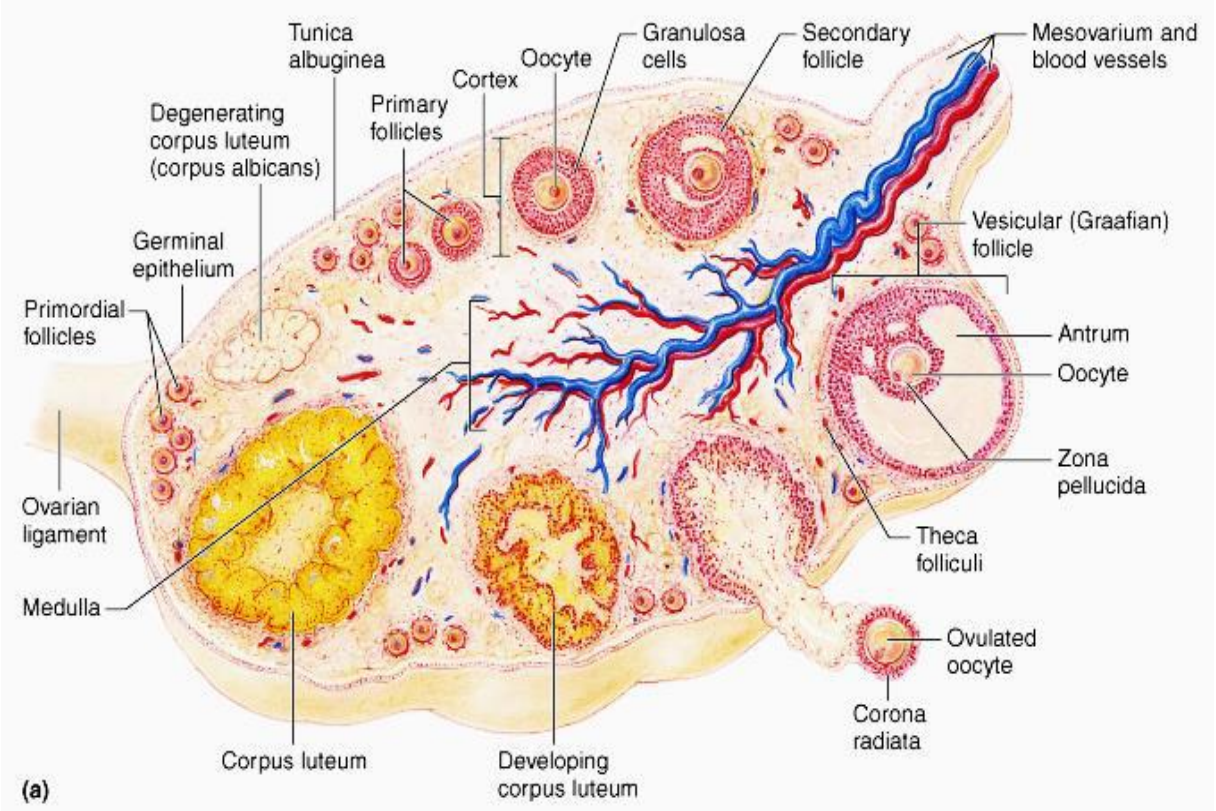
Ovulation occurs around 14 days before the onset of menstrual bleeding, which means that a woman with a 28-day cycle will ovulate around the 14th day of her cycle. However, if she has a longer cycle, ovulation will occur later. Ovulation is provoked by another signal sent by the hypophysis, the luteinizing hormone (LH) peak. During ovulation, the oocyte is extruded from the follicle, whose wall breaks, and is aspirated into the Fallopian tube. The oocyte now starts its migration towards the uterus.

Luteal phase

During this phase, the endometrium of the uterus is prepared for implantation of the embryo resulting from the fertilization of the oocyte by a spermatozoon. This processes dependent upon hormones released by the ruptured follicle from which the oocyte was expulsed.

The follicle is transformed into a corpus luteum (which means yellow body) and start to secrete a new hormone, progesterone until the placenta can take over production of progesterone.

ANATOMICAL REPRESENTATION OF OVARIES



Hence, progesterone is "pro gestational" and maintains the uterine lining during the course of pregnancy. If fertilization does not occur, the corpus luteum shrinks into corpus albicans and levels of both estrogen and progesterone decrease. The fall in progesterone level causes the endometrial lining to “break” resulting in vaginal bleeding. This is called **menstruation.**

ROLE OF HORMONES DURING MENSTRUAL CYCLE

The **hormonal cycle** facilitates maturation and rupture of the ovarian follicle results in the release of an ovum (the female reproductive or germ cell). Each month a series of changes take place which prepares the uterus for pregnancy. This cycle (**menstrual cycle**) is described below:

- The first day of menstruation (referred to as Day 1) occurs when levels of estrogen and progesterone are low. In response to these low levels, the hypothalamus secretes**Gonadotrophin releasing hormone (GnRH)** which

- FSH stimulates the development of many follicles within the ovary. One dominant follicle takes over. As it continues to grow, it produces increasing amounts of estrogen, which stimulates the release of LH, and inhibits FSH, which suppresses further follicular development.

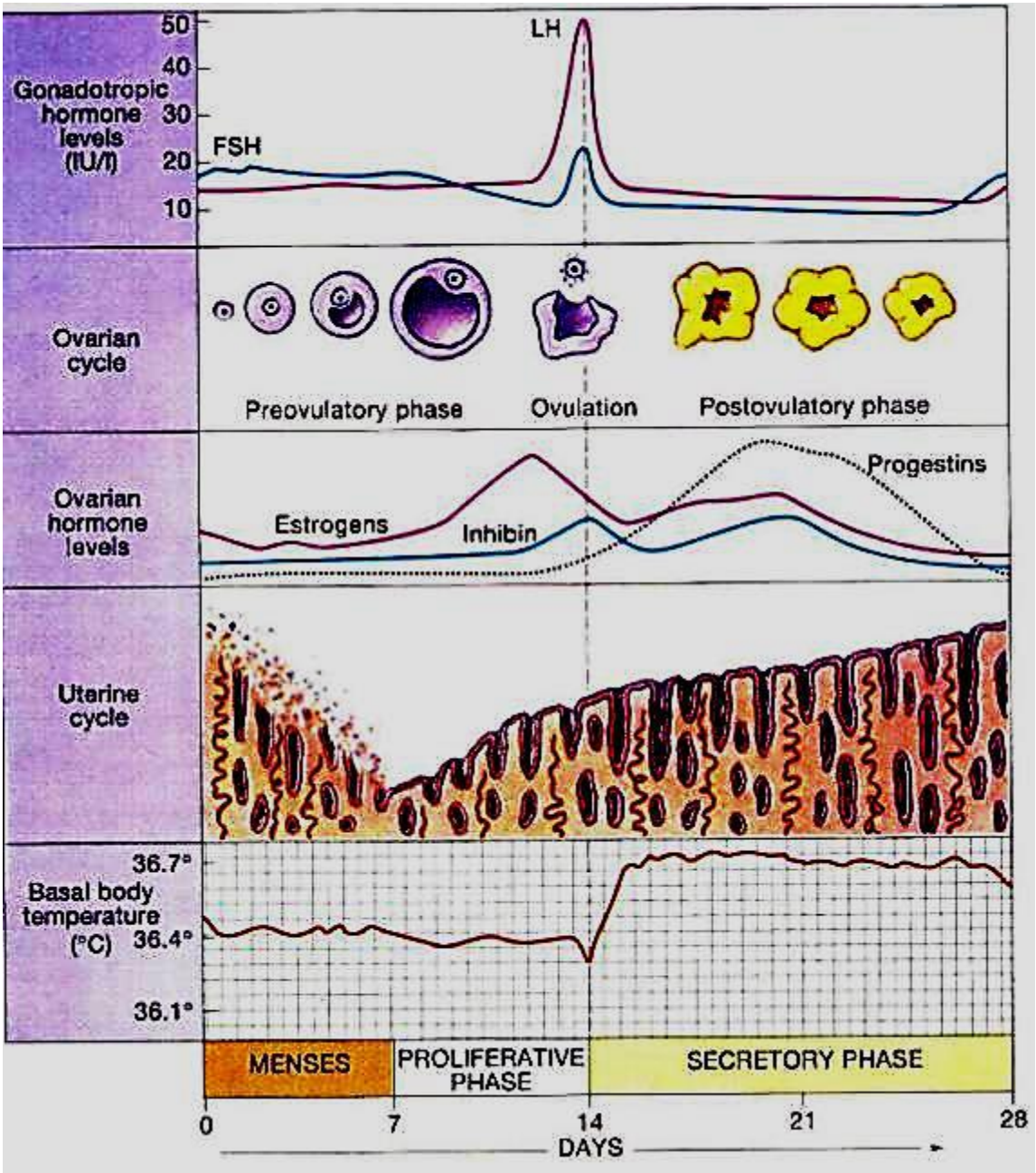
- When LH levels are highest (**LH surge**)**,** the ovarian follicle "ruptures" and releases an ovum, which is "swept" into the fallopian tube by hair-like projections called cilia that line the **fimbriae** (the fringe-like end of the fallopian tube that is closest to the ovary). This process is called ovulation. Increasing estrogen levels causes the **cervical mucous** (vaginal secretions) to become clear and profuse and the os to dilate. These two actions may facilitate the transport of semen (containing sperm) from the vagina, through the uterus, and into the fallopian tube.

- Following ovulation, the ruptured follicle is transformed into the **corpus luteum,** a glandular mass that continues to produce estrogen and higher levels of **progesterone.** The progesterone causes the endometrium to thicken, preparing it for implantation of a fertilized egg. If fertilization takes place during ovulation, progesterone level remains high, essential for the maintenance of the pregnancy.

- If fertilization does not occur, the corpus luteum shrinks into corpus albicans and levels of both estrogen and progesterone decrease. The fall in progesterone level cause the endometrial lining to "break" resulting in vaginal bleeding. This is called **menstruation, which marks the low point for estrogen activity and this leads to new cycle**. The average menstrual cycle is 28-35 days, and menstrual flow usually continues for three to seven days, although there are variations among women.

- Following menstruation, estrogen and progesterone levels are low, triggering the hypothalamus to once again release GnRH, starting the entire cycle again. If fertilization does take place, menstruation will not re occur for the duration of the pregnancy

Graphical representation of The reproductive cycle



Ovarian and Uterine Cycles in the Non pregnant Woman

Ovarian Cycle	Events	Uterine Cycle	Events
Follicular phase **(1-13 days)**	**FSH secretion begins.** **Follicle maturation occurs** **Estrogen secretion is prominent.**	**Menstruation** **(2-5 days)** **Proliferative phase** **(6-13) days**	**Endometrium breaks down.** **Endometrium rebuilds.**
Ovulation **(15-28 days)**	**LH spike occurs.**	---	---
Luteal phase **(15-28 days)**	**LH secretion continues.** **Corpus luteum forms.** **Progesterone secretion is prominent.**	**Secretory phase** **(15-28 days)**	**Endometrial thickens, and glands are secretory.**

POLYCYSTIC OVARIAN SYNDROME

INTRODUCTION:

Polycystic ovarian syndrome (PCOS) was first described by valisnere in 1721 as "Young, married peasant women, moderately obese, and infertile with two larger than normal ovaries, bumpy, shiny and whitish, just like pigeon eggs". The cyst related changes to the ovaries were described in 1844 [(11)].

In 1953, Stein and Leventhal described a symptom complex with anovulation and it called it polycystic ovarian disease (POD) [(12)].

PREVALANCE OF PCOS

PCOS occurs in 5% to 10% of women, making it one of the most common endocrine disorder[(13)]. PCOS is a heterogeneous endocrine disorder that affects about 1 in15 women worldwide[(14)]. The prevalence of Polycystic ovaries in Indian sub-continent Asian women was 52%[(15)]. PCOS exists commonly among women at reproductive age with an incidence rate of 6–10% [(16)].

Polycystic morphology seen in ultrasound is approximately 22% of women [(17)]. Hirsutism is a common problem in India as elsewhere in the world. Idiopathic hirsutism 38.7%, PCOS 37.3%. In India nearly 40% of women are affected by PCOS. But among them only 60% come to hospitals for treatment, when they recognize that they have got infertility [(18)].

DEFINITION

PCOS is a syndrome, which can be defined as a group of recognizable patterns of symptoms or abnormalities that indicate a particular medical situation. The current definition of PCOS requires the presence of two of the following three conditions: (i) Oligo and /or anovalation, (ii) Clinical and/or biochemical signs of hyper androgenism, and (iii) Polycystic ovaries-and the exclusion of other etiologies.

CAUSE

PCOS is a heterogeneous disorder of uncertain etiology such as [19,20]

1. Genetic cause: There is strong evidence that it is a genetic disease. Although specific gene associated with the condition have not yet been identified.

2. Hormonal imbalance: An imbalance in the release of the luteinizing hormone (LH) and the follicle stimulating hormone (FSH) from the pituitary has been implicated.

The LH / FSH ratio is altered and the secretion of LH is higher than that of FSH resulting in increased androgen, testosterone and dehydroepiandrosterone (DHEA) productions.

3. Insulin resistance: It is not solely a consequence of increased visceral obesity. Rather, obesity and hormonal abnormalities are thought to make additive contributions to insulin resistance. Functional insulin resistance is considered as consequence of defects in insulin-mediated glucose transport and signaling in adipocytes and myocyte. This may be the result of dysregulation in adipokine production and signaling from adipose tissues but the mechanism is incompletely understood.

4. **Intrauterine exposures:** Exposure to testosterone in utero may predispose to the later development of PCOS.

5. **Environment / lifestyle factors:** Several lifestyle factors and environmental exposures have been associated with more severe PCOS phenotype.

6. **Obesity:** Although obesity is not believed to cause PCOS, it is known to exacerbate the symptoms of the disease.

CLINICAL SYMPTOMS: The principle features of PCOS includes,

1. Irregular menstrual periods:

PCOS mostly produce oligomenorrhoea (few menstrual periods) or amenorrhoea (no menstrual periods) but other types of menstrual disorders may also occur [21].

2. Central obesity [22]: BMI > 30kg/cm2, waist line. ”

3. Reproductive manifestation [23]:

Subfertility or infertility this generally results directly from chronic an ovulation

4. Clinical hyperandrogenism:

The most common signs are acne and hirsuitism (male pattern of hair growth on face, chest, stomach or back) but it may produce hypermenorrhoea (very frequent menstrual periods), androgenic alopecia (Male-pattern baldness or thinning hair) or other symptoms [24]. Approximately three-quarters of patients with PCOS (by the diagnostic criteria of NIH/NICHD 1990) have evidence of hyperandrogemia [25].

5. Acanthosis nigricans:

It is due to insulin resistance (IR). Thick pigmented skin over the nape of neck, inner thigh and axilla.

HAIR-AN syndrome has been coined to describe the constellation symptoms of hyper androgenism, insulin resistance and acanthosis nigricans

6. Metabolic syndrome:

It is a cluster of endocrine disturbances like IR, dyslipidemia, obesity, hypertension, type 2 diabetes mellitus, atherosclerosis and endothelial dysfunction. PCOS women have an 11 fold higher risk of having above metabolic syndromes compared to age matched controls. Homocysteine levels are higher in women with PCOS [26].

7. Psychological problems:

It includes reduced quality of life, poor self-esteem, depression, anxiety.[27,28]

COMPLICATIONS OF PCOS

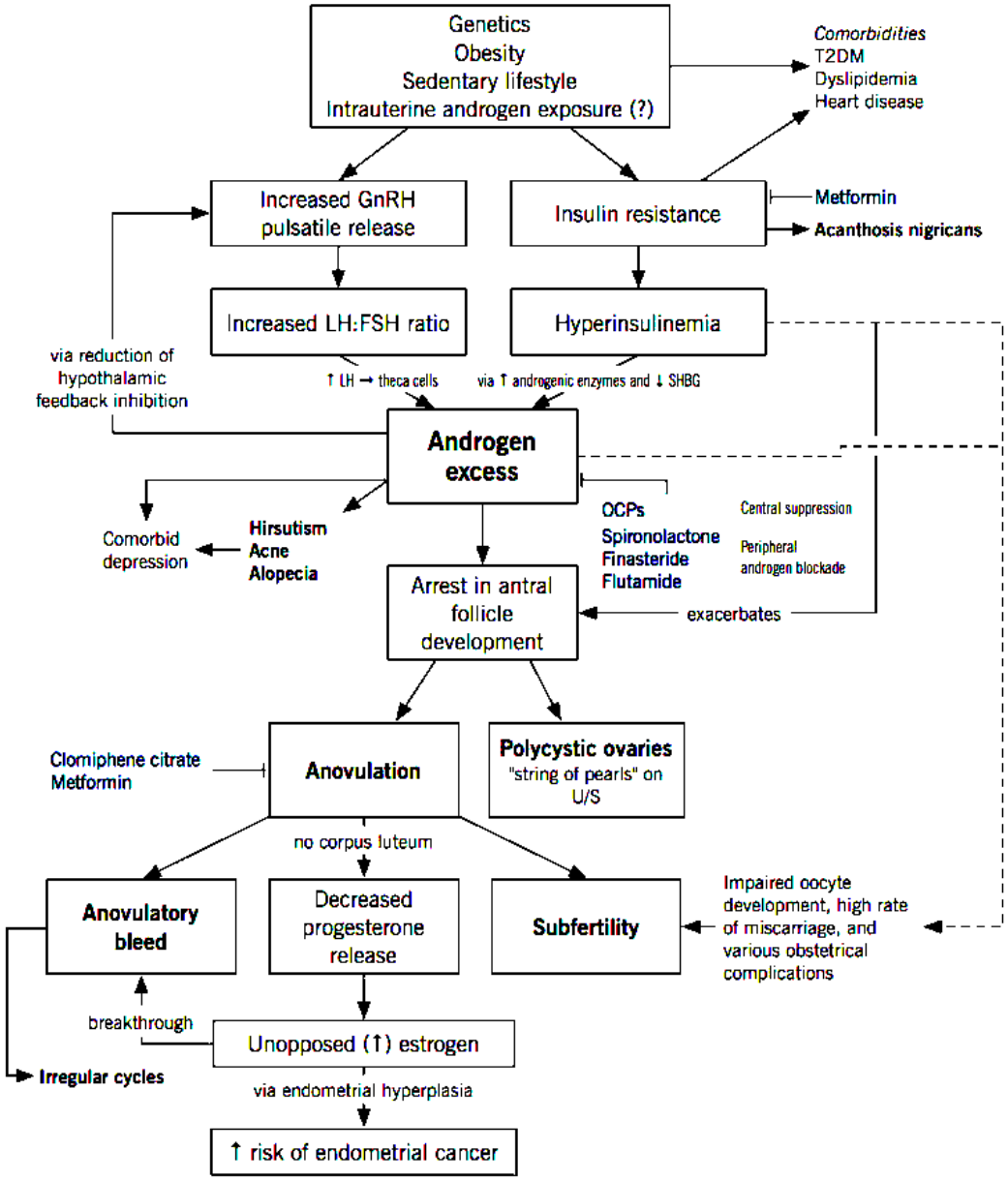
- Type 2 diabetes mellitus
- Hypertension
- Dyslipidemia - elevated triglycerides or decreased high-density lipoprotein (HDL),
- Cardiovascular disorder
- Anxiety and depression
- Sleep apnea
- Endometrial carcinoma

- Premature delivery
- Early miscarriage
- Gestational hypertension – pre eclampsia,
- Low birth weight or macrosomia.
- Gestational diabetes mellitus

PATHOPHYSIOLOGY

The "cysts" in polycystic ovaries are not true cysts, but rather antral follicles which have arrested in development. This is thought to occur because of hormonal abnormalities:

PATHOPHYSIOLOGY OF PCOS



Hyperandrogenism: Arrest occurs when the granulosa cells of the ovaries normally begin to produce estrogen by aromatizing androstenedione produced by the theca cells; excess 5a-reduced androgens in the ovaries are thought to inhibit the action of aromatase and therefore reduce estradiol synthesis, which is required for further maturation.

Hyperinsulinemia: Exacerbates ovarian hyperandrogenism by (1) increasing 17a-hydroxylase activity in theca cells and promoting androstenedione and testosterone production; (2) promoting LH- and IGF1-stimulated androgen production; and (3) elevating free testosterone by decreasing the production of sex hormone binding globulin (SHBG).

INVESTIGATIONS:

There is no single diagnostic test for PCOS. The diagnosis of PCOS is based on hyperandrogenism or chronic anovulation in the absence of specific pituitary and/or adrenal disease.

Ultrasonogram:

Ultrasound findings are confirmative of PCOS. Pelvic ultrasonography may be very helpful in the evaluation as well, but polycystic ovaries are not specific for PCOS with over 20% of "normal" women having this finding [(29)]. The number of follicles and ovary volume are important in the ultrasound evaluation.

The criteria for PCOS put forth by **Adams et al**. are the most often cited: The presence of ≥10 cysts measuring 2–8 mm around a dense core of stroma or scattered within an increased amount of stroma [(30)].

A recent proposal to modify these criteria has been put forth by **Jonard et al.**"Increased ovarian area (>5.5cm2) or volume (>11 mL) and/or presence of ≥12 follicles measuring 2 to 9 mm in diameter (mean of both ovaries)" [(31)].

These criteria had a specificity of 99% and a sensitivity of 75% for the diagnosis of PCOS.

Hormonal test:

- Prolactin
- Thyroid Function Test – Both are the key investigations to exclude other disorders.
- Testosterone level in patients with PCOS seldom exceeds 4.8 nmol/l. If it is greater than 4.8 nmol/l then further endocrinological investigation to exclude other causes of androgen hypersecretion eg., cushing syndrome, adrenal gland or ovarian tumour [(32)].
- FSH (Follicle Stimulating Hormone)
- LH (LH:FSH ratio may not be elevated in obese is suggestive of PCOS)
- Free androgen index (FAI) is the ratio of testosterone to sex hormone-binding globulin (SHBG) to assess androgen status [(14)]. If FAI level is above 5 it is an indicative for PCOS[(33)].
- Rarely DHEAS (Dehydroepiandrosterodione) values ≥800 μg/dL (21.7 μmol/L) highly suggestive of an adrenal dysfunction [(34)].
- 24-hour urine free cortisol - Mild elevations can be seen in PCOS with values ≥2 times the upper limit of normal more consistent with Cushing's syndrome.
- 17-hydroxyprogesterone - A morning, fasting, unstimulated level of <200 ng/dL (<6 nmol/L) in the follicular phase reliably excludes late-onset 21-hydroxylase deficiency.
- Further evaluation of levels ≥200 ng/dL involves adrenocorticotropic hormone (ACTH)-stimulation with an intravenous 250 μg dose and a 30 minute value (stimulated values ≥1,000 ng/dL (≥30 nmol/L) confirm the diagnosis)[(35)].

Biochemical Study:

- Fasting blood sugar
- Lipid Profile – HDL, LDL, VLDL and Triglyceride level
- Fasting insulin level – insulin resistance can be observed in 50-80% of people with PCOS.

- OGTT - It is extremely useful in categorizing patients' risk of type 2 diabetes mellitus may indicate impaired glucose tolerance in 15-33% of women with PCOS.

Laproscopy:

It is not only diagnostic but also therapeutic in destroying the cyst. Many patients with PCOS, particularly those who are having trouble becoming pregnant will have a laparoscopy. A laparoscopy is an operation whereby the patient is given a short general anaesthetic, a small cut is made in the umbilicus, and a telescope is inserted to acess the health of pelvic contents including the uterus, tubes, ovaries and to look for any associated endometriosis. At laparoscopy PCOS ovaries look rather like ping-pong balls.

Hysteroscopy:

Hysteroscopy is an operation whereby a fine telescope is used to look inside the cavity of the womb (uterus). This is particularly important where the patient has had significant abnormal bleeding. Abnormal areas in the uterus can be seen and specific biopsies taken to assess for cancerous or pre-cancerous changes.

Differential diagnosis

Other causes of irregular or absent menstruation and hirsutism should be investigated such as,

- Hypothyroidism
- Congenital adrenal hyperplasia (21-hydroxylase deficiency)
- Cushing syndrome
- Hyperprolactinemia
- Androgen secreting neoplasms
- Pituitary or adrenal disorders

PCOS has been reported in other insulin-resistant situations such as acromegaly

DIAGNOSIS:

The diagnosis of PCOS has been based on the history of oligomenorrhoea and/ or hyperandrogenism, either clinical or biochemical and / or polycystic ovaries on ultrasound.

TREATMENT

Metformin: Treatment of glucose intolerance, hyperinsulinemia, and anovulation. Reducing circulating insulin levels may secondarily reduce ovarian androgen synthesis.

Clomiphene citrate: For inducing ovulation.

Estrogen and progestin oral contraceptive (OCP) therapy: Treatment of acne, hirsutism and irregular menstrual cycles.

Lifestyle modification: May help attenuate all symptoms of PCOS and reduce the long-term risk of infertility, CVD and T2DM.

Anti-androgens (e.g. spironolactone, finasteride, flutamide): Treatment of acne and hirsutism.

Gonadotropin therapy: Recombinant FSH and hCG can be used to induce ovulation in cases where treatment with clomiphene citrate and metformin has been unsuccessful

Ovarian drilling: A laparoscopic surgical procedure that may be used to treat clomiphene citrate-resistant anovulation.

In vitro fertilization (IVF): Used for the treatment of infertility in women who have not responded to other therapies to induce ovulation.

Management:

It is the most effective and inexpensive approach, without adverse reactions. It consists in the practice of regular physical activity and in the adoption of a balanced diet. The loss of only 2-7% of weight improves almost all the parameters of PCOS by reducing androgen levels and improving ovarian function[(36)] . These effects are related to the reduction in insulin levels and improvement of insulin resistance [(37)].

DRUG REVIEW

The formulation Garpa vaayu ilagam contains eighteen ingredients. The properties of each ingredient were explained under the following headings like Suvai, Thanmai, Pirivu, Pothu gunam, Pharmacological action and Traditional uses.

1.வெண்சிவதை-Operculina *Turpethum,Linn*

சுவை- கைப்பு; **தன்மை**- வெப்பம்; **பிரிவு**-கார்ப்பு

கைப்புந் துவர்ப்புங் கலந்திருக்கும் பித்தத்தை

இப்புவியில் நாடொட்டா திவ்வளவோ-செப்புதரத்

தொள்ளைக் கிருமி தொலைக்குமிகு பேதிதரும்

வெள்ளைச் சிவதைதனை விள்.

Phytochemicals: Turpethin resin 4 to 10%, Glucoside, Turpethin [(39)].

Action: Purgative [(38)]

Pharmacological action: Anti-diabetic activity [(40)] , Immuno modulatory [(39)], Anti oxidant,
Anti cancer [(39)] , Anti microbial activity.

2.நிலவாகை - Cassia *senna, Linn.*

சுவை- கைப்பு; **தன்மை**- வெப்பம்; **பிரிவு**-கார்ப்பு

நிலவாரை யின்குணந்தான் நீகேள் மயிலே!

பலமூல வாயுவெப்பு பாவைச்-சிலகிரந்தி

பொல்லாத குன்மம் பொருமுமலக் கட்டுமுதல்

எல்லா மகற்றுமென எண்.

Phytochemicals: Anthroquinone glycoside [(41)](emodin, sennaside A & B, rhein), sodium potassium tartarate, salisilic acid, crisophanic acid, volatile oils, resin, calcium oxalate [(42)].
Action: Laxative [(38)]
Pharmacological action: Anti oxidant ,Anti diabetic, Anti hyperlipidemic activity.

3.கோரைக்கிழங்கு - Cyperus *rotundus,Linn*.

சீத சுரந்தீர்க்குஞ் செம்புனல்பித் தம்போகும்

வாத சுரந்தணிக்கும் வையகத்தில்- வேதைசெய்ய

வந்த பிணியை யெல்லாம் வாட்டுமுத் தக்காசு

கொந்துலவும் வார்குழலே! கூறு.

Phytochemicals: Alkaloids, Flavonoids, Tannins, Starch, Glycosides, Sesquiterpenes, Sitosterol, Fatty oils, Cyperene [(45)] .

Action: Astringent, Emmenagogue, Vermifuge, Stimulant, Tonic, Diuretic[(38)].

Pharmacological action: Anti diabetic, Anti diarrhoeal, Cyto protective, Anti oxidant[(45)].

4.சுக்கு - Zingiber *officinale, Rosc.*

சுவை - கார்ப்பு; **தன்மை** - வெப்பம்; **பிரிவு** -கார்ப்பு

சூலைமந்தம் நெஞ்செரிப்பு தோடமேப் பம்மழலை

மூலம் இரைப்பிருமல் மூக்குநீர்- வாலகப

தோடமதி சாரந் தொடர்வாத குன்மநீர்த்

தோடம்ஆ மம்போக்குஞ் சுக்கு.

Phytochemicals: Alkaloids, Flavanoids, Glycosides, Saponins, Carbohydrates, Proteins, Steroids, Terpenoids.

Action: Carminative, Stimulant, Stomachic [(38)] .

Pharmacological action: Hypolypidemicactivity [(46)], Anti-diabetic, Anti oxidant.

Traditional uses: Remove the outer covering of garlic, then boiled with ginger juice and mixed with sugar and make it into a paste and given with coconut oil will regularise the menstruation.

5.மிளகு - Piper *nigrum.Linn*

சுவை- கைப்பு,கார்ப்பு; **தன்மை**- வெப்பம்; **பிரிவு** -கார்ப்பு

சீதசுரம் பாண்டு சிலேத்மங் கிராணிகுன்மம்

வாதம் அருசிபித்தம் மாமூலம்-ஓதுசன்னி

யாசபஸ் மாரம் அடன்மேகம் காசமிவை

நாசங் கறிமிளகினால்.

Phytochemicals: Alkaloids, Phenols, Tannins, Coumarins, Essential oil, Carbohydrates, Proteins, Amino acids.

Action: Anti-vatha, Carminative, Resolvent, Stimulant [(38)]

Pharmacological action: Anti oxidant, Anti-diabetic [(47)].

6.திப்பிலி - Piper *longum*

சுவை- இனிப்பு; **தன்மை** - வெப்பம்; **பிரிவு** -இனிப்பு

இருமல் குன்மம் இரைப்பு கயப்பிணி

ஈளை பாண்டு சந்நியாசம் அரோசகம்

பொருமல் ஊதை சிரப்பிணி மூர்ச்சைநோய்

பூரிக் குஞ்சல தோடம் பீலிகமும்

வரும லப்பெருக் கோடு மகோதரம்

வாதம் ஆதிமுத் தோடஞ் சுரங்குளிர்

பெருமாலைப்புரி மேகப் பிடகமும்

பேருந் திப்பிலிப் பேரங்குரைக்கவே.

Phytochemicals: Alkaloids, Tannins, Coumarins, Carbohydrates, Proteins, Aminoacids, Phenols, Essential oil.

Action: Carminative, Stimulant [(38)]

Pharmacological action: Anti-diabetic, Anti oxidant [(49)], Anti hyperlipidaemic [(50)].

7.கடுக்காய் - Terminalia *chebula.Retz*

சுவை - துவர்ப்பு, இனிப்பு,புளிப்பு,கார்ப்பு,கைப்பு; **தன்மை** - வெப்பம்; **பிரிவு** - இனிப்பு

தாடை கழுத்தக்கி தாலு குறியிவிடப்

பீடை சிலிபதமுற் பேதிமுடம்- ஆடையெட்டாத்

தூலமிடி புண்வாத சோணிகா மாலையிரண்

டாலமிடி போம்வரிக்காயால்.

Phytochemicals: Tannins, Triterpenoids, Phenolic.

Pharmacological action: Anti-diabetic, Anti oxidant [(51)], Hypolipidaemic activity.

8.நெல்லிக்காய் - Phyllanthus *emblica.Linn*

சுவை - புளிப்பு,துவர்ப்பு,இனிப்பு; **தன்மை** - தட்பம்; **பிரிவு** -இனிப்பு

பித்தமன லையம் பீனிசம்வாய் நீர் வாந்தி

மத்தமலக் காடும் மயக்கமுகில்-ஒத்தவுரு

வில்லிக்கா யம்மருங்கா மென்னாட்கா லந்தேர்ந்தே

நெல்லிக்கா யம்மருந் துணீ.

Phytochemicals: Alkaloids, Steroids, Flavanoids, Saponins, Anthroquinones, Tannins.

Actions: Astringent, Laxative, Refrigerant, Diuretic.

Pharmacological acions: Anti oxidant, Anti-diabetic, Spasmolytic action, Lipid lowering effect.

9.தான்றிக்காய் - Terminalia *bellerica.Roxb.*

சுவை - துவர்ப்பு; **தன்மை** - வெப்பம்; **பிரிவு** -இனிப்பு

சிலந்திவிடம் காமியப்புண் சீழான மேகங்

கலந்துவரும் வாதபித்தங் காலோ-டலர்ந்துடலில்

ஊன்றிக்காய் வெப்ப முதிரபித் துங்கரக்குந்

தான்றிக்காய் கையிலெடுத் தால்.

Phytochemicals: Tannins, Anthroquinone, Alkaloids, Glycosides, Phytosterols, Triterpenoids, Flavanoids, Carbohydrates, Proteins, Amino acids, Cardiac glycosides.

Actions: Laxative, Tonic, Astringent, Expectorant.

Pharmacological actions:Anti-fertility, Anti hypercholestrolemic [(52)], Hypoglycaemic.

10.கண்டதிப்பிலி - Piper *longum*

சுவை - ,கார்ப்பு; **தன்மை** - வெப்பம்; **பிரிவு** -இனிப்பு

தாகபித்தஞ் சோகந் தணியாச் சுரமிருமல்

மேகங் குரற்கம்மல் மெய்க்கடுப்பும்- ஏகுங்காண்

திப்பிலிமூ லங்கண்டத் திப்பிலிய தாம்நறுக்குத்

திப்பிலியென் றேயொருக்காற் செப்பு.

11.இந்துப்பு - Sodium chloride impure

வேறுபெயர் - சந்திரனுப்பு, மதியுப்பு

அட்டகுன்மம் மந்தம் அசிர்க்கரஞ்சூர் சீதப்பித்தம்

துட்டவையம் நாடிப்புண் தோடங்கள்- கெட்டமலக்

கட்டுவிட விந்துப்பைக் காமியநோய் வன்கரப்பான்

விட்டுவிட விந்துப்பை விள் [(53)].

Actions: Laxative

12.ஓமம் - Carum copticum Benth&Hook.f

சுவை - கார்ப்பு; **தன்மை** - வெப்பம்; **பிரிவு** - கார்ப்பு

சீதசுரங் காசஞ் செரியாமந் தம்பொருமல்

பேதியிரைச் சல்கடுப்பு பேராமம்-ஓதிருமல்

பல்லொடுபல் மூலம் பகமிவைநோ யென்செயுமோ?

சொல்லொடுபோம் ஓமமெனச் சொல்.

Phytochemicals: Thymol

Actions: Antispasmodic, Carminative, Stomachic, Stimulant, Tonic, Antiseptic, Sialogogue.

Pharmacological actions: Antioxidant [(54)], Anti-diabetic

13.குரோசாணி ஓமம் - Hyoscyamus *niger Linn*

சுவை - கார்ப்பு, சிறுகைப்பு; **தன்மை** - வெப்பம்; **பிரிவு** - கார்ப்பு

வெகுமூத் திரம்வாதம் வீரியநட் டம்புண்

உகுபேதி யுட்கடுப்பினோடே-மிகுகரப்பான்

தீராக் கபமிவைபோம் செய்யகு ரோசாணியென்றால்

வாரா மயக்கமுறு மால்.

Phytochemicals: Hyoscyamine

Actions: Hypnotic, Sedative, Anodyne, Antispasmodic, Mild diuretic

Pharmacological actions: Anti tumor, Antioxidant.

Traditional uses: It is used also as a pessary in painful affections of the uterus

14.வாய்விளங்கம் - Embelia *ribes.Burm.f*

சுவை - கைப்பு; **தன்மை** - வெப்பம்; **பிரிவு** - கார்ப்பு

பாண்டுகுட்டம் குன்மம் பருந்தூல நோய்வாதந்

தீண்டு திரிவிடஞ் சிரந்துண்டம்-பூண்டமடி

நோவிளங்கக் காட்டாத நுண்கிருமி யாசனப்புண்

வாய்விளங்கங்காட்டவிருமார்.

Phytochemicals: Phenolic compounds, Tannins, Alkaloids, Saponins, Carbohydrates, Proteins, Oil, Fats, Mucilage

Actions: Anthelmintic, Carminative, Stomachic, Stimulant.

Pharmacological actions: Anti-diabetic, Anti oxidant [(55)], **Oestrogenic action.**

15.அதிவிடயம் - Aconitum *hetrophyllum Wall-ex Royle*

சுவை - கைப்பு; **தன்மை** - வெப்பம்; **பிரிவு** - கார்ப்பு

அதிவி டயம்சர்க்க ராற்புதநோய் வெப்பு

கொதிமருவு பேதியொடு கோழை- எதிர்வாந்தி

என்றுரைக்கும் நோய்க்கூட்டம் இல்லா தகற்றிவிடும்

குன்றை நிகர்முலையாய்! கூறு.

Phytochemicals: Alkaloids, Saponins, Tannins, Flavanoids, Phenols and Lipids

Actions: Stomachic, Astringent, Febrifuge, Aphrodisiac, Tonic, Aniperiodic

Pharmacological actions: Anti inflammatory[(56)]

16.மாசிக்காய் - Quercus *infectoria oliver*

சுவை - துவர்ப்பு; **தன்மை** - தட்பம்; **பிரிவு** - கார்ப்பு

அக்கரங்கள் போக்கிவிடும் மாறாத வெப்பகற்றும்

மெய்க்குறுதி மாசிக்காய் மென்மேலும் - தக்கதொரு

பாலர்கண நோய்போக்கும் பன்மேக முந்தொலைக்கும்

வேலனைய கண்ணாய்! விளம்பு.

Phytochemicals: Tannins (50-70%), Gallic acid, Ellagic acid, Syringic acid and Methyl

betulate.

Actions: Astringent, Styptic, Tonic

Pharmacological actions: Anti-inflammatory, Anti bacterial [57], Emollient

17.சிற்றாமணக்கு எண்ணெய் - Ricinus *communis,Linn*

சுவை - சிறுகைப்பு; **தன்மை** - வெப்பம்; **பிரிவு** - கார்ப்பு

ஆமணக்கு நெய்யால் நலமுண்டாம் யாவர்க்கும்

பூமணக்கு மேனி புரிகுழலே- வாய்மணக்கக்

கொள்ளில் வயிறுவிடுங் கோரமுள்ள வாயுவறும்

உள்ளில்வரு குன்மம்போ மோது.

Actions: Laxative, Antivatha, Emollient [38].

Pharmacological actions: Anti-inflammatory, Anti-bacterial**, Laxative**, Emollient

Traditional uses: 30 ml of castor oil mix either with milk or ginger juice and drink. This will result in loose motion. This will cure loss of appetite and menses problems.

MATERIALS AND METHODS

MATERIALS AND METHODS:

1. Authentication of raw drug

The raw drugs were purchased from a well reputed indigenous drug shop. The raw drugs were identified and authenticated by the Asst. Professor in Medicinal botany, NIS and Indhuppu (Sodium chloride impura), from Dept. of Pharmacognosy in Siddha Central Research Institute, Chennai.

2. Purification of raw drugs

The following drugs were purified as per the siddha literature ;

1. Root of Sivathai *(*Operculina *turpethum.Linn*[59]

   .- steamed with milk anddried.

2. Root of Nilavagai *(*Cassia *senna,Linn)*[60]

   - steamed with milk and dried.

3. Koraikizhangu *(*Cyperus *rotandus)*[61]

   - Remove the outer skin and shadow dry.

4. Sukku (Zingiber *officinalis.Rosc*) [60]

   - Peel off the outer skin

5. Milagu *(*Piper *nigrum.Linn*)[60]

   -Soak it in butter milk for three hours and dry it.

6. Thippili(Piper *longum.Linn*)[60]

   -Soak it in butter milk for three hours and dry it.

7. Kadukkai *(*Terminalia *chebula.Retz)*[61]

   -Discard the seed and collect the rinds alone for use.

8. Thaantrikkai (Terminalia *bellarica.Roxb)* [61]

   - Discard the seed and collect the rinds alone for use.

9. Nellikkai *(*Phylanthus *embilica.Linn)* [60]

   - Remove the seed and collect the rinds alone for use.

10. Kanda Thippili(Piper *longum.Linn*)[59]

    -Soak it in butter milk for three hours & dry.

11. Indhuppu *(*Sodium *chloride impura)*[53]

    -soaked in viniger for three days and dried in sunlight.

12. Omam (Carum *coptium.Benth&Hook.f*)[60]

    -Soak it in clear calcium carbonate filtrate and dry it.

13. Kadugu Rogini (Picrorhiza *scrophulariflora,Pennell)*[60]

    -Dry it in shade.

14. Vaaivilangam *(*Embelia *ribes.Burm)* [60]

    -Remove the waste from it and dry it in shade.

15. Athividayam (Aconitum *heterophyllum Wall-ex Royle)*[60]

    -Dry it in shade

16. Maasikai *(*Quercus *infectoria.Oliver*)[60]

    -Dry it in shade.

17. Raipur Sugar *(*Brown *sugar)*[59]

    -Dissolved in water and filter it.

18. Sitramanakku ennai *(*Ricinus *communis.Linn)*[60]

    -Filter it.

19. Water-Filter it.

3.Preparation of trial drug

Garpavaayuilagam: Ref: Vaithiya saarasangiragam,P.no-59

Ingredients:

1. Sivathai vaer *(*Operculina *turpethum.Linn)*	-	150 varagan (630 gm)
2. Nilavagaivaer*(*Cassia *senna,Linn)*	-	150 varagan (630gm)
3. Koraikizhangu*(*Cyperus*rotandus,Linn)*	-	33 varagan (138.2 gm)
4. Sukku *(*Zingiber *officinalis.Rosc)*	-	1.7 gm
5. Milaghu *(*Piper *nigrum.Linn)*	-	1.7gm
6. Thippili *(*Piper *longum.Linn)*	-	1.7 gm
7. Kadukai *(*Terminalia *chebula.Retz)*	-	1.7 gm
8. Thaantrikkai *(*Terminalia *bellarica.Roxb)*	-	1.7 gm
9. Nellikkai *(* Phylanthus *embilica.Linn)*	-	1.7 gm
10. Kanda Thippili(Piper *longum.Linn*)	-	1 kazhanju (5.1 gm)
11. Indhuppu *(*Sodium *chloride impura)*	-	1 kazhanju (5.1 gm)
12. Omam (Carum *coptium.Benth&Hook)*	-	1 kazhanju (5.1 gm)
13. KaduguRogini*(*Picrorhiza*scrophulariflora,Pennell)*	-	1 kazhanju (5.1gm)
14. Vaaivilangam *(*Embelia *ribes.Burm)*	-	1 kazhanju (5.1gm)
15. Athividayam (Aconitum *heterophyllum Wall-ex Royle*	-	1 kazhanju (5.1 gm)
16. Maasikai *(Quercus infectoria.Oliver*)	-	1 kazhanju (5.1 gm)
17. Raipur Sugar(Brown sugar)	-	5 palam (175 gm)
18. Sitramanakkuennei*(Ricinuscommunis,Linn)*	-	1 padi (1.3 litre)
19. Water	-	Suffiecient quantity

Method of preperation: The purified raw drugs from 1 to 16 were made into fine powder. The powder were added to the sugar syrup (i.e 175 gms of powdered sugar required quantity of water was added and boiled till it reache syrup consistency) and mix it well until it reach to ilagam consistency. Then Castor oil-1.3litre were added to the above mixture. The prepared drug was stored in air tight glass container .

4. Physiochemical analysis of trial drug

Sample discription: **Garpavaayu ilagam.**

COLOUR

About 5 gm of Garpavaayu ilagam was taken in a clean glass beaker and tested for its colour by viewing again a white opaque back ground under direct sunlight.

ODOUR

About 5 gm of the Garpavaayu ilagam was placed in 100 ml of beaker and tested for its odour by wafting the air above the beaker.

LOSS ON DRYING AT 100 ºC

5 gms of Garpavaayu ilagam was heated in a hot oven at 100º c to a constant .The percentage of loss of weight was calculated.

pH

The pH of the Garpavaayu ilagam was estimated as per the method prescribed in the Indian standard (IS) -6940(1982). One gram of the Garpavaayu ilagam was taken in to a 100ml graduated cylinder containing about 50 ml of water and filled up to the mark with water. The cylinder was stopped and shaken vigorously for two minutes and the suspension was allowed to settle for hour at 25ºc to 27ºC about 25 ml of the clear aqueous solution was transfered in to a 50 ml beaker and tested for pH using DIGISUN digital pH meter (DIGISUN electronics, Hyderabad, India)

DETERMINATION OF ASH VALUE

Weighed accurately 2gms of the Garpavaayu ilagam in tarred platinum or silica dish and incinerate at a temperature not be exceeding 450ºC until free from corban cooled and weighed calculate the percentage of ash with reference of the air dried drug was then calculated.

WATER SOLUBLE ASH

To the Gooch crucible containing to the total ash, added 25 ml of water and boiled for 5 minutes. Collected the insoluble matter in a sintered glass crucible for 15 minutes at a temperature not exceeding 450º c subtract the weight off the insoluble matter from the weight of the ash the difference of the weight represents the water soluble ash. Calculate the percentage of water soluble ash with the reference to the air dried drug.

ACID INSOLUBLE ASH

Boiled ash 5minutes with 25 ml of 1:1 dil. Hcl collect the insoluble matter Gooch crucible on an ash less filter paper wash without water and ignited, cooled in a desiccators and weighed , calculated the percentage of insoluble ash with reference to the air dried drug.

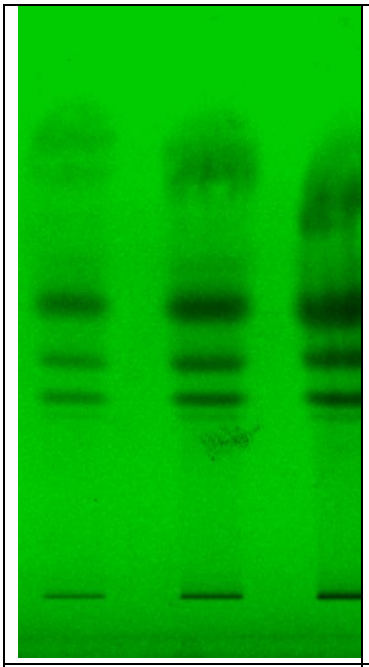
STANDARDISATION OF REPORTS

S.NO	PARAMETER	MEAN
1.	Loss on Drying at 105 C	11.77%
2.	Total ash	3.33%
3.	Water soluble Ash	1.27%
4.	Acid insoluble Ash	0.48%
5.	Water Soluble extractives	52.17%
6.	Alcohol soluble extractives	44.31%
7.	pH	5.6
8.	Total solid	88.23%
9.	Fat content	12.18%
10.	Reducing sugar	Nil
11.	Total sugar	30.78%

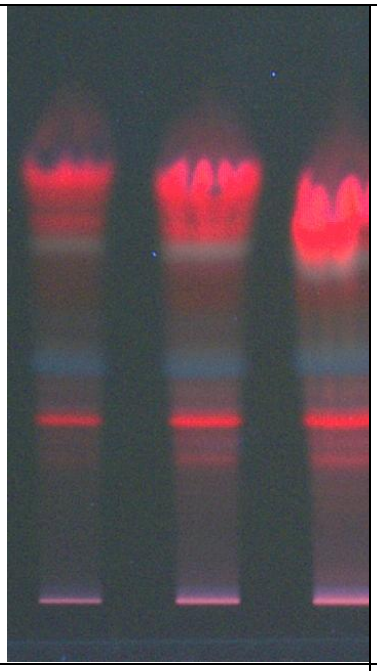
HPTLC DOCUMENTATION

Stationary Phase - Silica Gel 60 F_{254}

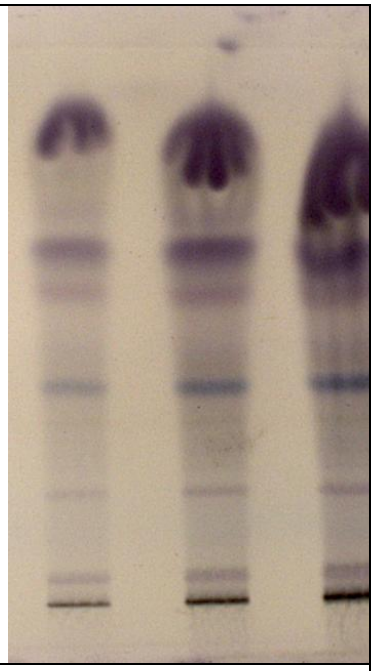
Mobile Phase - Toluene : Ethyl Acetate : Formic Acid (5: 2: 0.5 v/v/v)



λ = 254 nm



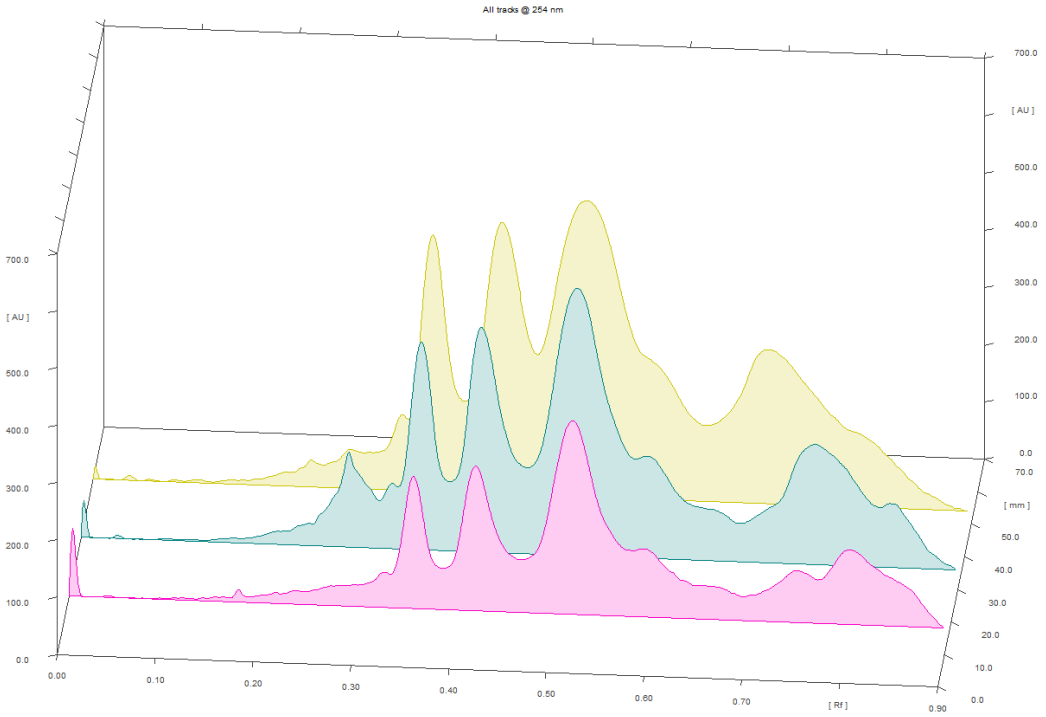
λ = 366 nm



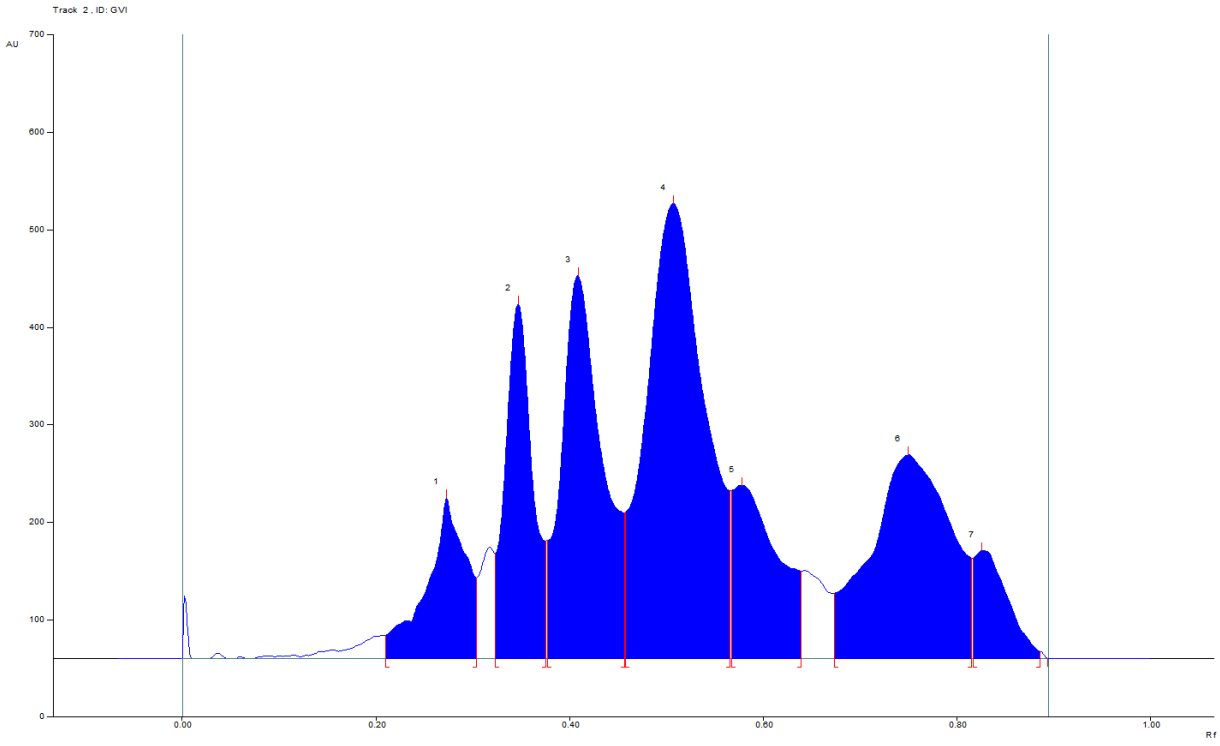
λ = 575 nm (Derivatized)

Color	**R_f value(s)**	**Color**	**R_f value(s)**	**Color**	**R_f value(s)**
Green	0.32	Light pink	0.24	Purple	0.04
Green	0.35	Dark pink	0.32	Purple	0.19
Green	0.42	Bluish grey	0.41	Blue	0.37
Green	0.50	Light pink	0.55	Pink	0.53
Green	0.58	Light pink	0.58	Purple	0.61
Green	0.76	Light Grey	0.62		
		Light Pink	0.65		
		Light Pink	0.71		

3D Chromatogram @ 254 nm:



HPTLC Chromatogram @ 254 nm:



Peak Table @ 254 nm:

Track 2, ID: GVI

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.21 Rf	23.9 AU	0.27 Rf	165.2 AU	8.76 %	0.30 Rf	82.9 AU	5761.5 AU	7.24 %
2	0.32 Rf	108.1 AU	0.35 Rf	363.9 AU	19.29 %	0.38 Rf	20.8 AU	8866.1 AU	11.14 %
3	0.38 Rf	121.1 AU	0.41 Rf	393.0 AU	20.83 %	0.46 Rf	49.8 AU	14535.4 AU	18.27 %
4	0.46 Rf	150.2 AU	0.51 Rf	466.8 AU	24.74 %	0.57 Rf	72.3 AU	24628.4 AU	30.95 %
5	0.57 Rf	172.4 AU	0.58 Rf	177.9 AU	9.43 %	0.64 Rf	89.9 AU	7291.4 AU	9.16 %
6	0.67 Rf	67.2 AU	0.75 Rf	209.1 AU	11.08 %	0.82 Rf	02.7 AU	15099.3 AU	18.97 %
7	0.82 Rf	102.8 AU	0.83 Rf	111.0 AU	5.88 %	0.89 Rf	7.4 AU	3394.0 AU	4.27 %

BIOCHEMICAL ANALYSIS

S.No	EXPERIMENT	OBSERVATION	INFERENCE
	1.Test For Acid Radicals		
1.	**Test For Sulphate :** 2ml of the above prepared extract is taken in a test tube to this added 2ml of 4% ammonium oxalate solution.	No cloudy appearance present	Absence of Sulphate
2.	**Test For Chloride:** 2ml of the above prepared extract is added with 2ml of dil- HNO_3 till the effervescence ceases. Then 2 ml of silver nitrate solution is added.	Cloudy appearance present	Presence of Chloride
S	**Test For Phosphate:** 2ml of the extract is treated with 2ml of ammonium molybdate solution and 2ml of con.HNO_3	No cloudy yellow appearance present.	Absence of Phosphate
4.	**Test For Carbonate:** 2ml of the extract is treated with 2ml magnesium sulphate solution	No Cloudy appearance present	Absence of Carbonate
5.	**Test For Fluoride & Oxalate:** 2ml of extract is added with 2ml of dil. Acetic acid and 2ml calcium	No cloudy appearance present.	Absence of fluoride and

	chloride solution and heated.		oxalate
6.	**Test For Nitrate:** 1gm of the substance is heated with copper turning and concentrated H2So4 and viewed the test tube vertically down	No Brown gas is evolved	Absence of Nitrate
7.	**Test For Sulphide:** 1gm of the substance is treated with 2ml of con. HCL	No Rotten Egg Smelling gas evolved	Absence of Sulphide
8.	**Test For Nitrite:** 3 drops of the extract is placed on a filter paper, on that - 2 drops of acetic acid and 2 drops of Benzidine solution is placed.	No Characteristic changes	Absence of Nitrite
9.	**Test For Borate:** 2 Pinches of the substance is made into paste by using sulphuric acid and alcohol (95%) and introduced into the blue flame.	Bluish green colour flame not appeared	Absence of Borate
	II. Test For Basic Radicals		
1.	**Test For Lead:** 2ml of the extract is added with 2ml of potassium iodine solution.	No yellow precipitate is obtained.	Absence of Lead

2.	**Test For Copper:** 2ml of extract is added with excess of ammonia solution.	No blue color precipitate formed.	Absence of Copper
3.	**Test For Aluminium:** To the 2ml of extract sodium hydroxide is added in drops to excess.	No characteristic changes.	Absence of Aluminium
4.	**Test For Iron:** a. To the 2ml of extract add 2ml of ammonium thiocyanate solution b. To the 2ml of extract 2ml ammonium thiocyanate solution and 2ml of con HNO_3 is added	Mild red colour appear Blood red colour appeared.	Presence of Iron Presence of iron
5.	**Test For Zinc:** To 2ml of the extract sodium hydroxide solution is added in drops to excess	White precipitate is not formed	Absence of Zinc
6.	**Test For Calcium:** 2ml of the extract is added with 2ml of 4% ammonium oxalate solution	Cloudy appearance and white precipitate is obtained	Presence of Calcium
7.	**Test For Magnesium:** To 2ml of extract sodium hydroxide solution is added in drops toexcess.	White precipitate is not obtained	Absence of Magnesium

8.	**Test For Ammonium:** To 2ml of extract few ml of Nessler's reagent and excess of sodium hydroxide solution are added.	No Brown colour appeared	Absence of Ammonium
9.	**Test For Potassium:** A pinch of substance is treated with 2ml of sodium nitrite solution and then treated with 2ml of cobalt nitrate in 30% glacial acetic acid.	No Yellowish precipitate is obtained.	Absence of Potassium
10.	**Test For Sodium**: 2 pinches of the substance is made into paste by using HCl and introduced into the blue flame of Bunsen burner.	Yellow colour flame appeared	Presence of Sodium
11.	**Test For Mercury**: 2ml of the extract is treated with 2ml of sodium hydroxide solution.	No yellow precipitate is obtained	Absence of Mercury
12.	**Test For Arsenic:** 2ml of the extract is treated with 2ml of sodium hydroxide solution.	No brownish red precipitate is obtained	Absence of Arsenic
	III. Miscellaneous		
1.	**Test For Starch:** 2ml of extract is treated with weak iodine solution	No Blue colour developed	Absence of Starch
2.	**Test For Reducing Sugar:** 5ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and	Brick red colour developed	Presence of Reducing sugar

	added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.		
3.	**Test For The Alkaloids:** a) 2ml of the extract is treated with 2ml of potassium lodide solution. b) 2ml of the extract is treated with 2ml of picric acid. c) 2ml of the extract is treated with 2ml of phosphotungstic acid.	Yellow colour developed	Presence of Alkaloid
4.	**Test For Tannic Acid:** 2ml of extract is treated with 2ml of ferric chloride solution	Black precipitate is obtained	Presence of Tannic acid
5.	**Test For Unsaturated Compound:** To the 2ml of extract 2ml of Potassium permanganate solution is added.	Potassium permanganate is not decolourised	Absence of unsaturated compound
6.	**Test For Amino Acid:** 2 drops of the extract is placed on a filter paper and dried well..	No Violet colour developed	Absence of Amino acids
7.	**Test For Type Of Compound:** 2ml of the extract is treated with 2 ml of ferric chloride solution.	No Brown colour developed No red colour developed	Absence of Oay quinole, Pinephrine and Pyro catechol Anti pyrine,Alipathic

			amino acids and meconic acid are absent.
		No violet colour developed	Salicylate and resorcinol are absent.
		No Blue colour developed.	Morphine, Phenol cresol and hydroquinone are absent

Preliminary Qualitative Phytochemical tests procedure and inter pretation of results

s.no	Constituents	Inference
1.	**Calcium**	Present
2.	**Sulphate**	Absent
3.	**Chloride**	Present
4.	**Carbonate**	Absent
5.	**Sodium**	Present
6.	**Iron**	Present
7.	**Phosphate**	Absent
8.	**Tannic acid**	Present
9.	**Sugars**	Present
10.	**Alkaloids**	Present
11	**Fluoride**	Absent
12	**Oxalate**	Absent
13	**Aluminium**	Absent
14	**Zinc**	Absent
15	**Magnesium**	Absent
16	**Ammonium**	Absent
17	**Mercury**	Absent
18	**Arsenic**	Absent

19	**Silicate**	Absent
20	**Lead**	Absent
21	**Copper**	Absent
22	**Starch**	Absent

The bio chemical analysis of ***Garpavaayu ilagam***had shown the presence of Calcium, chloride, Iron, Sugars, Alkaloid, Tannic acid, Unsaturated compound.

Clinical trial

Screening of PCOD patients:

Patient reporting at the NIS, OPD of Maruthuvam with clinical features of amenorrhoea, oligomenorrhoea, obesity, irregular menstruation, and infertility will be subjected to screening test and documented using screening proforma. The patients who are enrolled are informed about the study trial drug, possible outcomes and the objectives of the study in their own language and terms understandable to them and the informed consent would be obtained from them in the consent form.

Patient recruitment

Inclusion

- Age: 20-40 years
- Patients who are having the clinical symptoms of Oligomenorrhoea (or) Amenorrhoea (or) Dysmenorrhoea.
- Patient willing to undergo Ultrasound abdomen & routine blood investigation.
- USG pelvis showing polycystic ovaries.
- Patient willing to participate in trial and signing in consent form

Exclusion

- H/O hypertension
- H/O Diabetes mellitus
- H/O cardiac disease
- Pregnancy and lactation
- H/O thyroid dysfunction
- Chronic kidney disease
- Fibroid uterus
- H/O use of HRT in one year before.

- Presence of any systemic illness (e.g.Anaemia,)

Conduct of clinical trial

Study design

Study type: An Open Clinical trial

Study Place:

OPD & IPD Of theAyothidass Pandithar Hospital ,
National Institute of Siddha,
Tambaram sanatorium,
Chennai-47.

Study Period **:** 12 months

Sample size **:** 40 patients

Conduct of the study

The trial drug was given by the investigator in the OP department of Maruthuvam, NIS, Chennai. On the first day the trial drug Garpa vaayu ilagam was given for 7 days medicine-7days drugholiday. The patients were asked to have a regular treatment in the OP department once in 14 days for 3 months. In every visit the clinical assessment was recorded in the prescribed Proforma (form no:II A). The laboratory investigation was done before and after treatment and recorded in the prescribed format (form no: III).

At the end of the trial the patients were advised to come for follow up for 2 months for observation.

Data Management:

- After enrolling the patient in the study, a separate file for each patient will be opened and all forms will be filed in the file. Study No. and Patient No. will be entered on the top of file for easy identification. Whenever the study patient visits OPD during the study period, the respective patient's file will be taken and necessary recordings will be made at the assessment form or other suitable forms.
- The screening forms will be filed separately.
- The Data recordings will be monitored for completion by Guide (HOD, Dept. of Maruthuvam), SRO (Statistics) and the adverse event will be monitored by

the members of the Pharmacovigilance department of NIS. All forms will be further scrutinized in presence of Investigator by Sr.Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results is permitted for unbiased reports.

Data analysis

All collected datas will beentered into the computer and manually cross checked the correctness of the data entry. The clinical symptoms and laboratory investigation of blood and urine will be analysed by comparing the data before and after treatment by paired test and chi-square test will be employed to study the efficacy of treatment.

OBSERVATION

OBSERVATION AND RESULTS

1. Age incidence

2. Marital status

3. Parity

4. Religion distribution

5. Distribution of cases by Paruvakaalam

6. Distribution of cases by Thinai

7. Dietary habits

8. Distribution of cases based on incidence of infertility

9. Body built (based on BMI)

10. Occupational distribution

11. Positive family history for the disease

12. Chronicity of illness

13. Treatmental history other than siddha treatment

    a)For treating infertility

    b) For irregular menstruation

14. Thegi

15. Derangement in mukkutram

    15. a Derangement in Vatham

    15. b Derangements in Pitha kutram

    15. c Derangements in Kaba kutram

16. Kanmenthiriyam involvement

17. Kosangal

18. Disturbance in Udal thathukkal

19. Envagai thervu

    19. a. Naadi

    19. b. Neikkuri (oil on urine sign)

20. Clinical symptoms before treatment

    20.a. Intermenstrual score before treatment

21. Out Come Measurement Before And After Treatment

    21. a. Changes in USG after treatment

    21.b. IMP score Before and After treatment

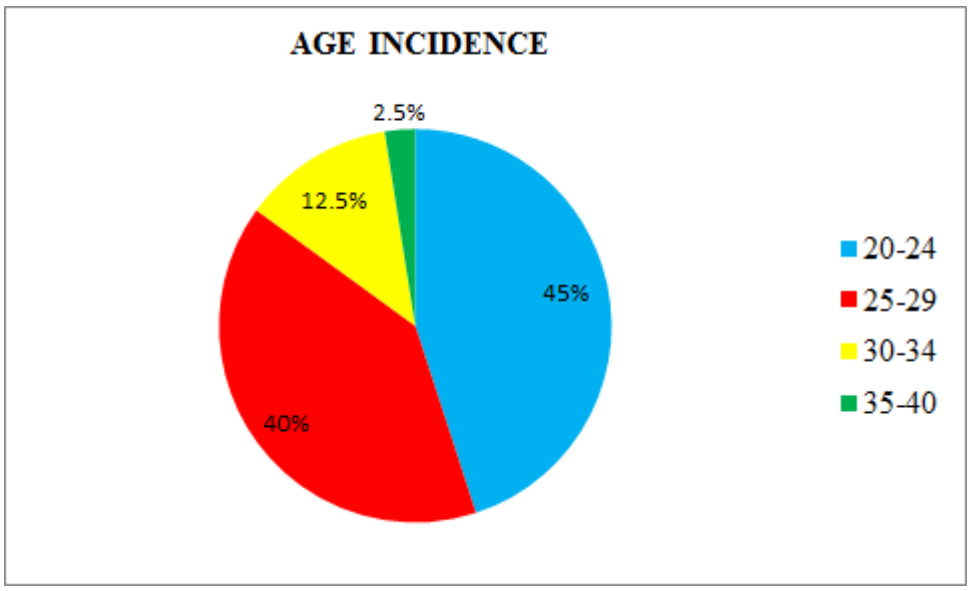
22. Clinical symptoms before and after treatment

23. BMI before and after treatment

1.AGE INCIDENCE

Table: 1

Age (Year)	No of cases	Percentage
20-24	18	45%
25-29	16	40%
30-34	5	12.5%
35-40	1	2.5%
Total	40	100%

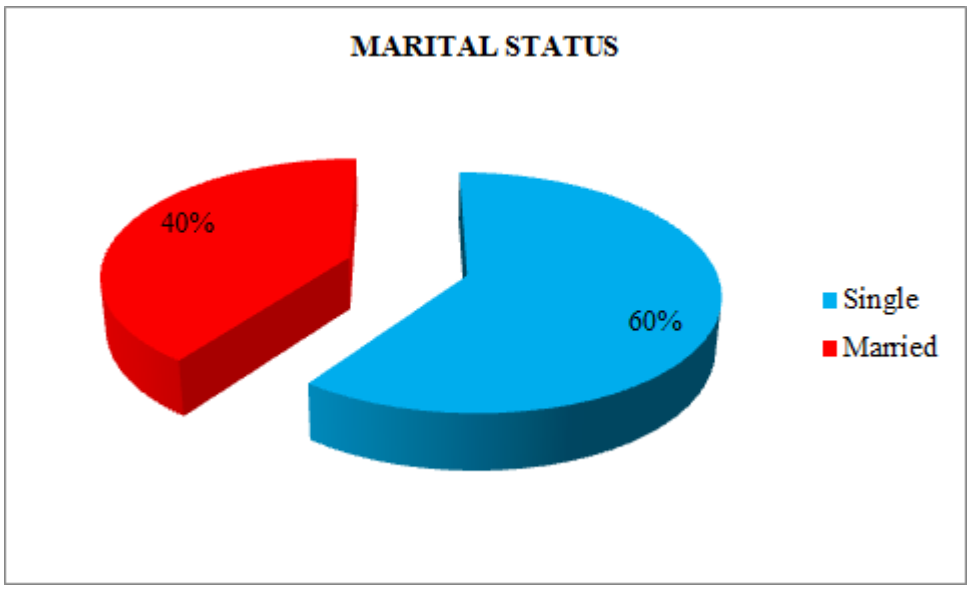


Observation: Among 40 cases, 18 cases(45%) were in the age group of 20-24 years, 16 cases(40%) in the age group of 25-29 years, 5 cases(12.5%) were in the age group of 30-34 years and 1case (2.5%) were in the age group of 35-40 yrs.

2. MARITAL STATUS

Table : 2

Marital status	No of case	Percentage
Single	**24**	**60%**
Married	**16**	**40%**
Total	**40**	**100%**



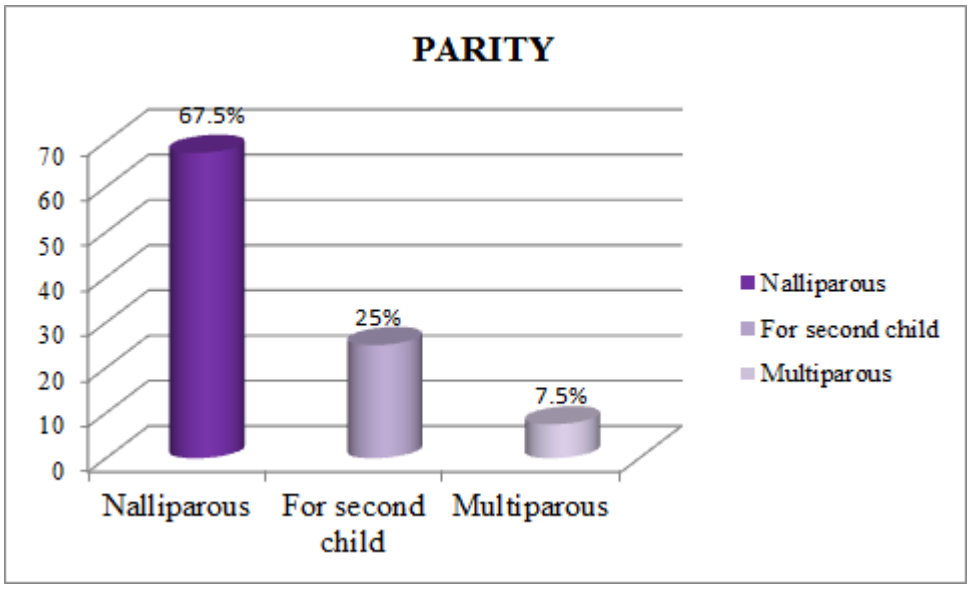
Observation:

Among the 40 patients selected, 24 cases (60%) were married and 16 cases(40%) were single.

3.PARITY

Table: 3

Parity	No of case	Percentage
Multiparous	**3**	**7.5%**
2 nd child	**10**	**25%**
Nulliparous	**27**	**67.5%**
Total	**40**	**100%**

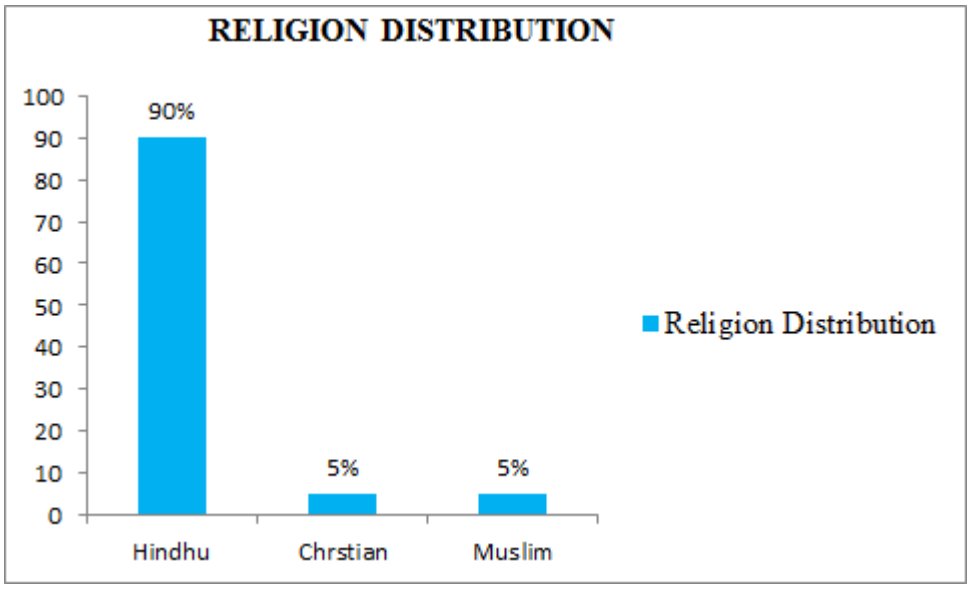


Observation: Out of 40 cases, 27 cases (67.5%) were found to be Nulliparous,10 cases (25%) were seeking for second child and 3cases(7.5%) were in Multiparous.

4. RELIGION DISTRIBUTION:

Table: 4

Religion	No of case	Percentage
Hindhu	**36**	**90 %**
Christian	**2**	**5 %**
Muslim	**2**	**5 %**
Total	**40**	**100 %**

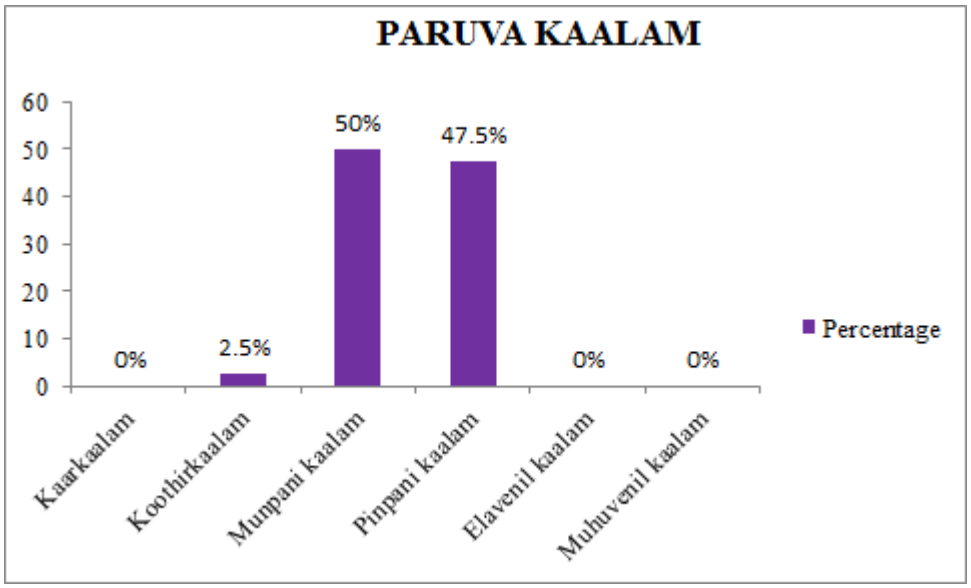


Observation: Among 40 patients, 36 cases (90%) were Hindu, 2cases(5%) were christian and 2 cases(5%) were Muslim**.**

5. PARUVA KAALAM (SEASON)

Table: 5

SI.No	Paruva Kaalam	No. of cases	Percentage
1	Kaar Kaalam (Aug 17- Oct 17)	**0**	**0 %**
2	Koothir Kaalam (Oct 18 – Dec 15)	**1**	**2.5 %**
3	Munpani Kaalam (Dec 16 – Feb 12)	**20**	**50 %**
4	Pinpani Kaalam(Feb 13 – Apr 13)	**19**	**47.5 %**
5	Elavenil Kaalam (Apr 14 – Jun 16)	**0**	**0 %**
6	Muthuvenil Kaalam (Jun 17 – Aug 16)	**0**	**0 %**
	Total	**40**	**100 %**

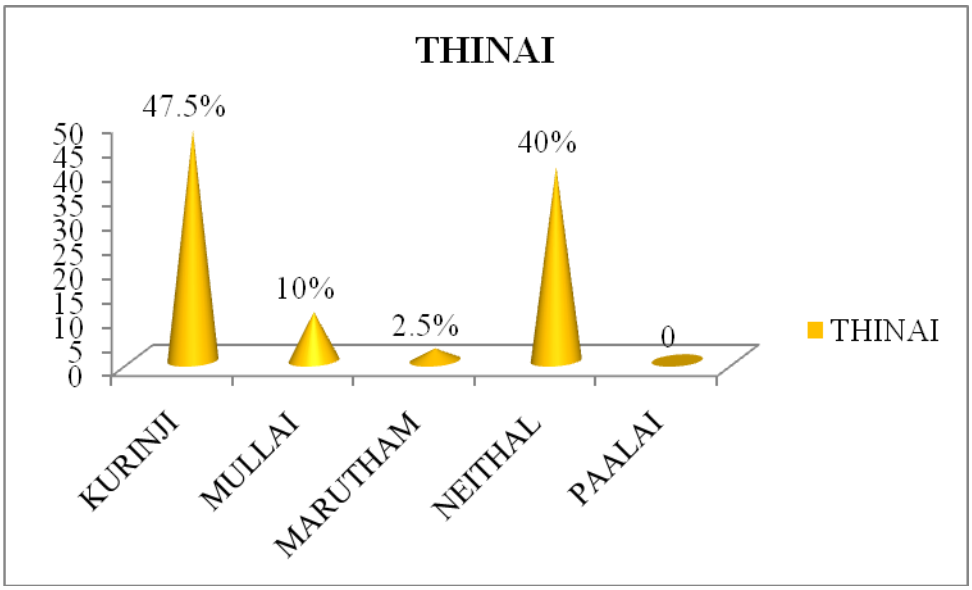


Observation: Out of 40 cases, 20 cases(50%) the treatment period was Munpani kaalam, 19 cases(47.5%) Pinpani kaalam and 1case(2.5%) koothirkaalam.

6. THINAI:

Table: 6

Thinai (Land)	**No of cases**	**Percentage**
Kurinji (Hill)	19	47.5 %
Mullai (Forest)	4	10 %
Marutham (Fertile)	1	2.5 %
Neithal(Coastal)	16	40 %
Paalai(Desert)	0	0 %
Total	40	100 %

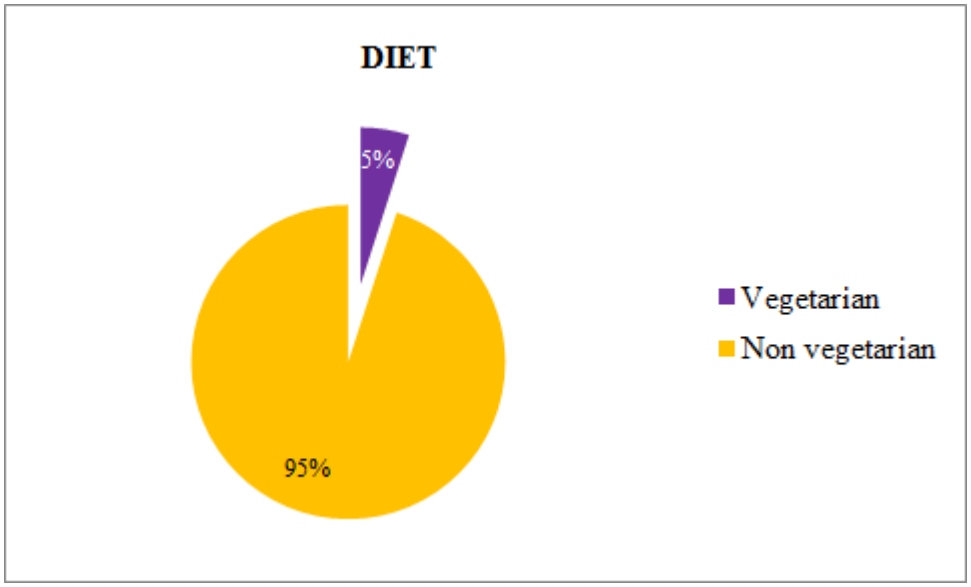


Observation: Out of 40 cases, 19cases (47.5%) were from the land Kurinji, 16 cases (40%) were from Neithal, 4 cases(10%) were from Mullai and 1 case (2.5%) from Marutham.

7. DIET

Table: 7

Dietery Habit	No of cases	Percentage
Vegetarian	2	5 %
Non - vegetarian	38	95 %
Total	40	100 %

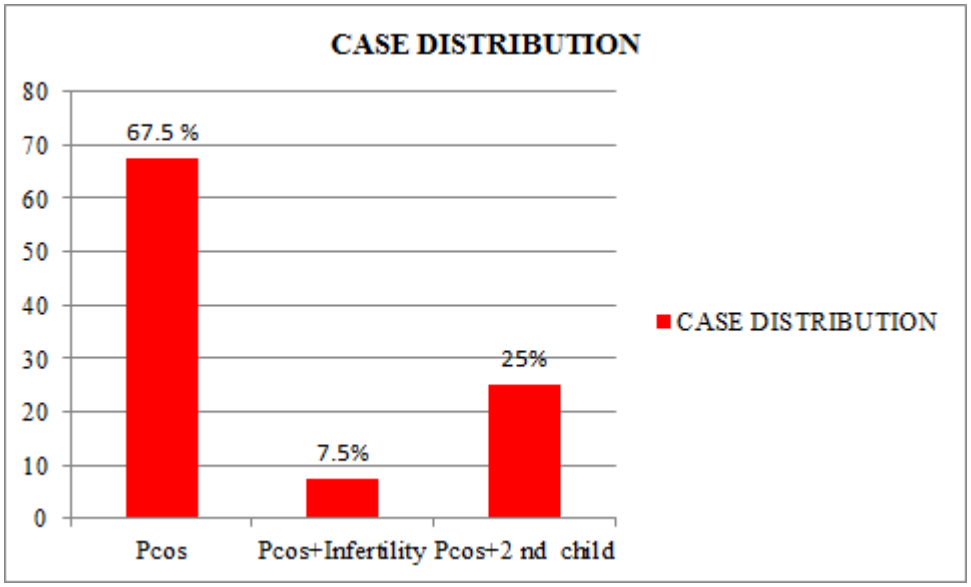


Observation: Among 40 patients, 38 (95%) cases were non vegetarian, and 2 (5%) cases were vegetarian.

8. CASE DISTRIBUTION

Table: 8

Case distribution	No of cases	Percentage
PCOS	**27**	**67.5 %**
PCOS along with infertility	**3**	**7.5 %**
PCOS and for 2 nd child	**10**	**25 %**
Total	**40**	**100 %**

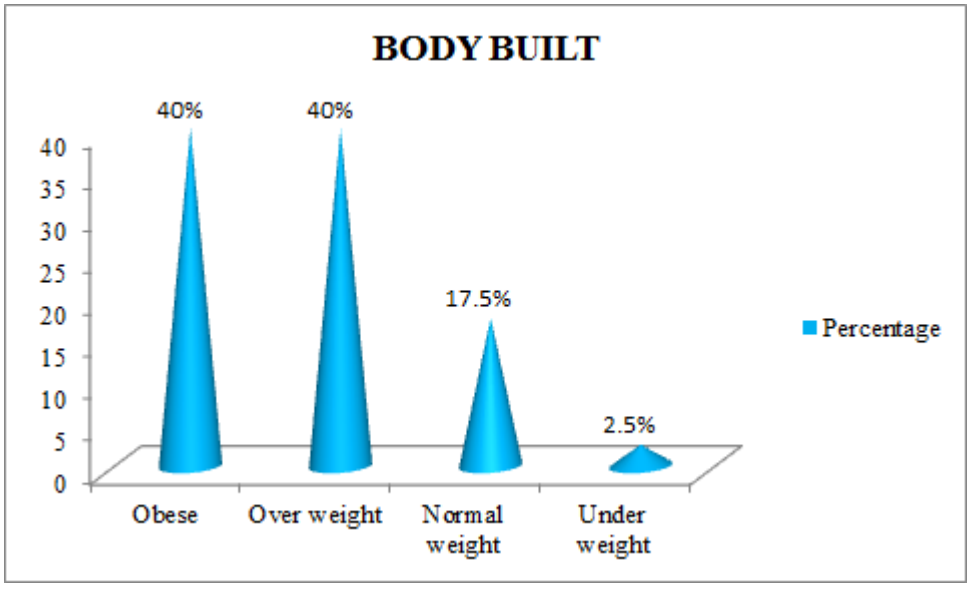


Observation: All the 40 patients had PCOS. Among them 27 cases (24 single and 3 married women) ie., 67.5% were diagnosed as PCOS only, 3cases (3 married women ie., 7.5%) were PCOS with Maladu (1º infertility) and 10 cases were PCOS with kathalimaladu (seeking for second child ie., 25%).

9. BODY BUILT:

Table: 9

BODY BUILT Based on BMI	**No of cases**	**Percentage**
Obese (>30)	16	40 %
Over weight (25-30)	16	40 %
Normal weight (21-25)	7	17.5 %
Under weight (Below 20)	1	2.5 %
Total	40	100 %

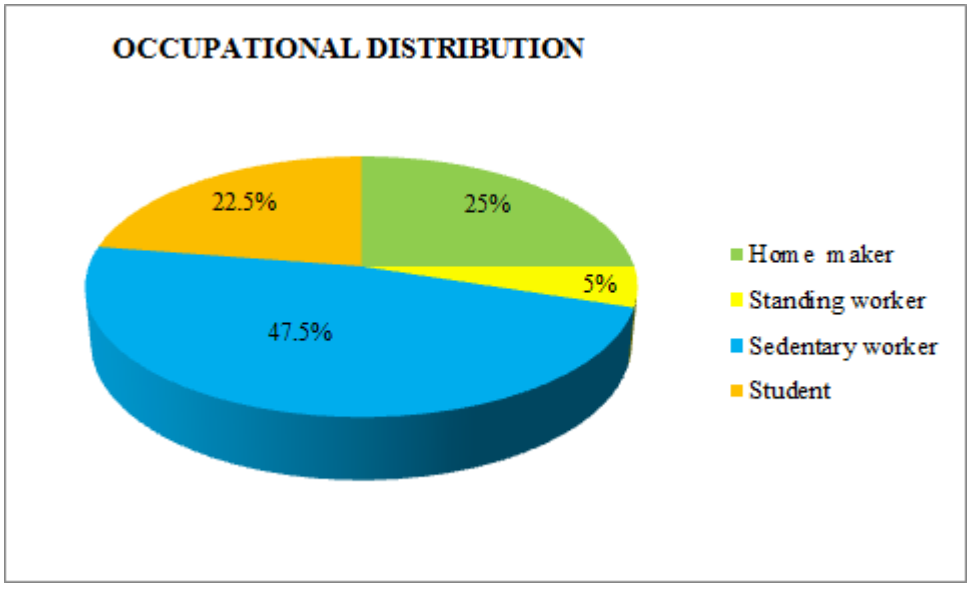


Observation: Among the 40 cases, 16 cases(40%) were obese, 16 cases(40%) were of over weight, 7 cases (17.5%) were normal weight and 1case(2.5%) comes under under weight category.

10. OCCUPATIONAL DISTRIBUTION

Table: 10

Nature of work	No of cases	Percentage
Home Maker	10	25 %
Standing work style	2	5 %
Sedentary work style	19	47.5 %
Student	19	22.5 %
Total	40	100 %

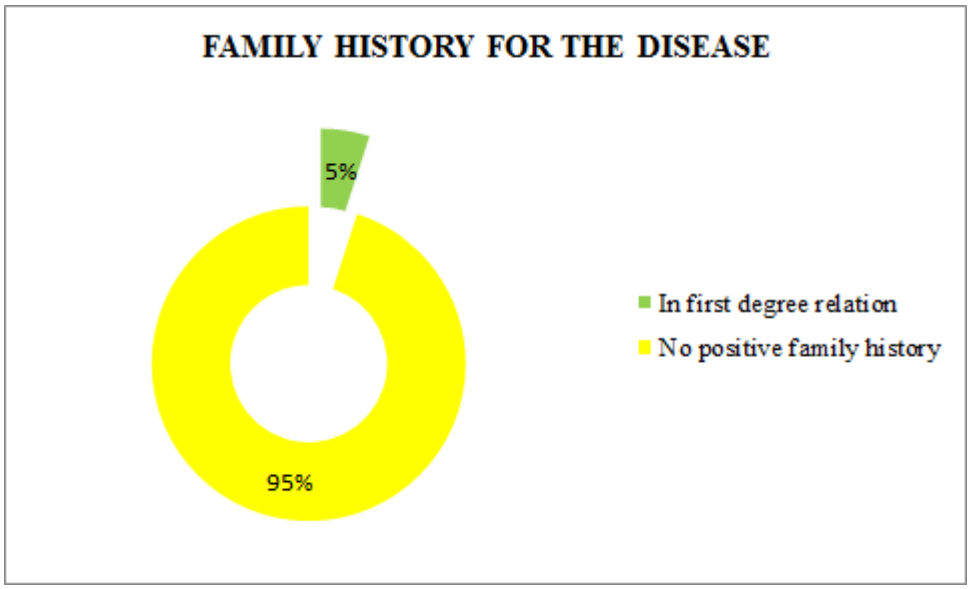


Observation: Among the 40 patients the incidence were more in sedentary workers ie., 19 cases(47.5 %) , next in home working 10 cases(25%) , next in students 9 cases (22.5%) and finally in standing workers 2 cases(5%).

11. POSITIVE FAMILY HISTORY FOR THE DISEASE

Table:11

Family history for the disease	No of case	Percentage
In 1 st degree relationship	**2**	**5 %**
No positive family history	**38**	**95 %**
Total	**40**	**100 %**



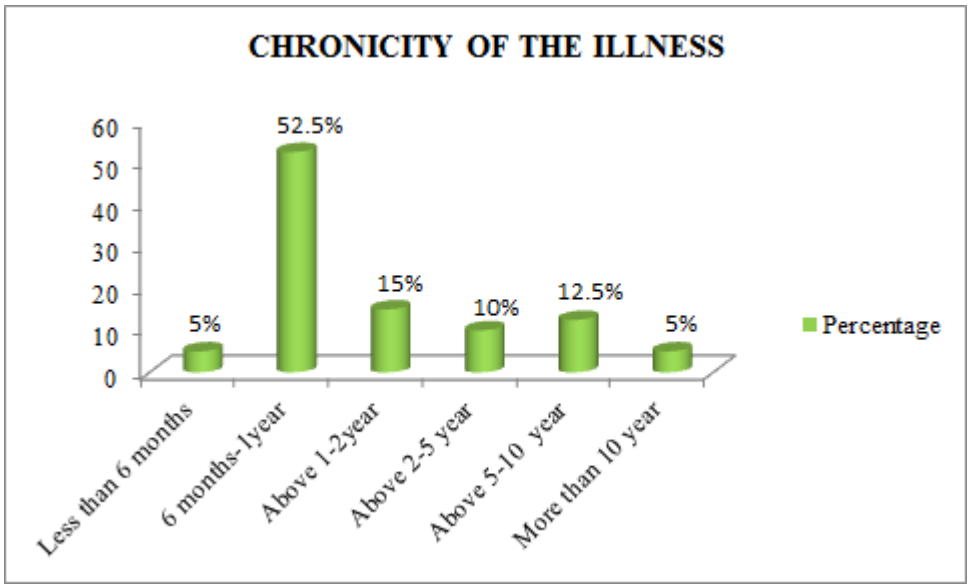
Observation: Positive familial history was seen in only 2 cases (5%) of patients and the other 38 cases (95%) have no relevant family history.

12. CHRONICITY OF ILLNESS:

a) Irregular menstruation:

Table: 12 (a)

Chronicity of illness	No. of cases	Percentage
Less than six months	**2**	**5 %**
6 months - 1 year	**21**	**52.5 %**
Above 1 - 2 year	**6**	**15 %**
Above 2 – 5 year	**4**	**10 %**
Above 5 – 10 year	**5**	**12.5 %**
More than 10 year	**2**	**5 %**
Total	**40**	**100 %**

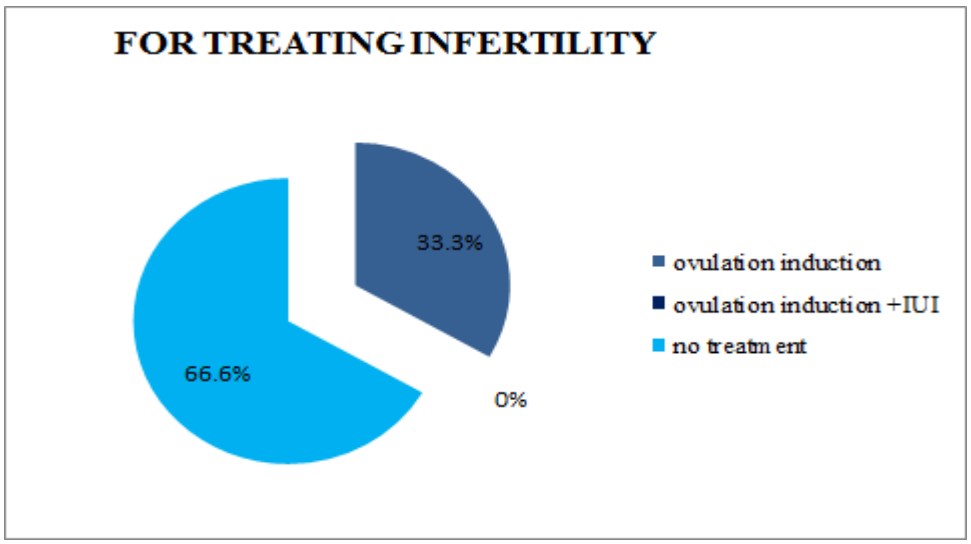


Observation: Among 40 patients, 21 cases (52.5 %) the duration of illness was between 6months – 1 yr, 2 cases(5%) was less than 6 months, 6cases(15%) were between 1-2 years, 4 cases(10%) the duration was between 2-5 yrs, 5 cases(12.5%) between 5-10 yrs and 2 cases (5%) the duration was more than 10 years.

13. TREATMENTAL HISTORY OTHER THAN SIDDHA:

Table: 13a (For treating infertility)

Various treatmental history	No of cases	Percentage
Ovulation induction	**1**	**33.33**
Ovulation induction + IUI	**0**	**0 %**
Not undergone any treatment before	**2**	**66.66 %**
Total	**3**	**100 %**

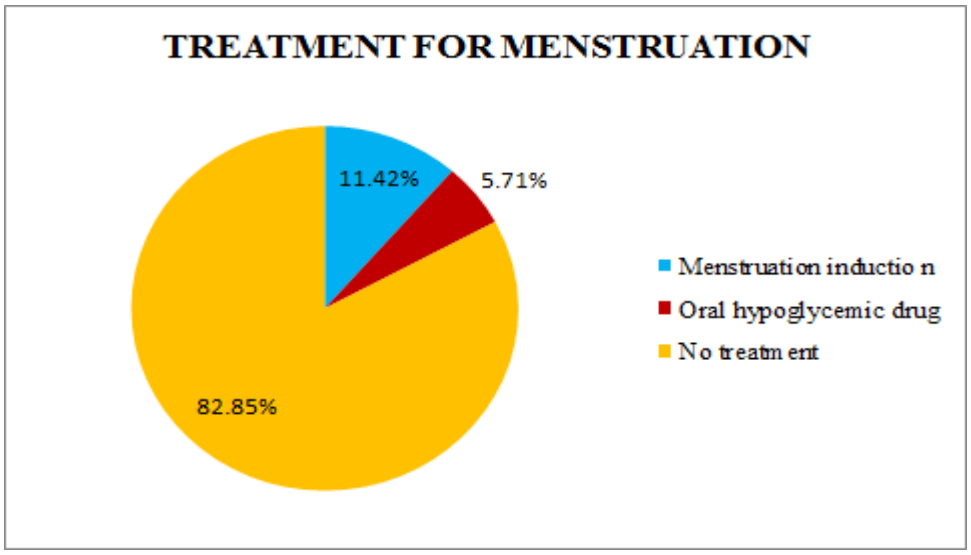


Observation: Among the 3 patients, 1 case (33.33%) only underwent ovulation induction

And 2 cases (66.66%) has not taken any treatment.

Table: 13b (For irregular menstruation)

Various treatmental history	No of cases	Percentage
Menstruation induction	**4**	**11.42 %**
Oral hypoglycemic drug	**2**	**5.71 %**
Not undergone any treatment before	**29**	**82.85 %**
Total	**35**	**100 %**



Observation: Among the 35 patients, 29 cases (82.85%) were not taken any treatment, 4 cases (11.42%) underwent menstruation induction and 2 cases(5.71%) were under oral hypoglycaemic drug.

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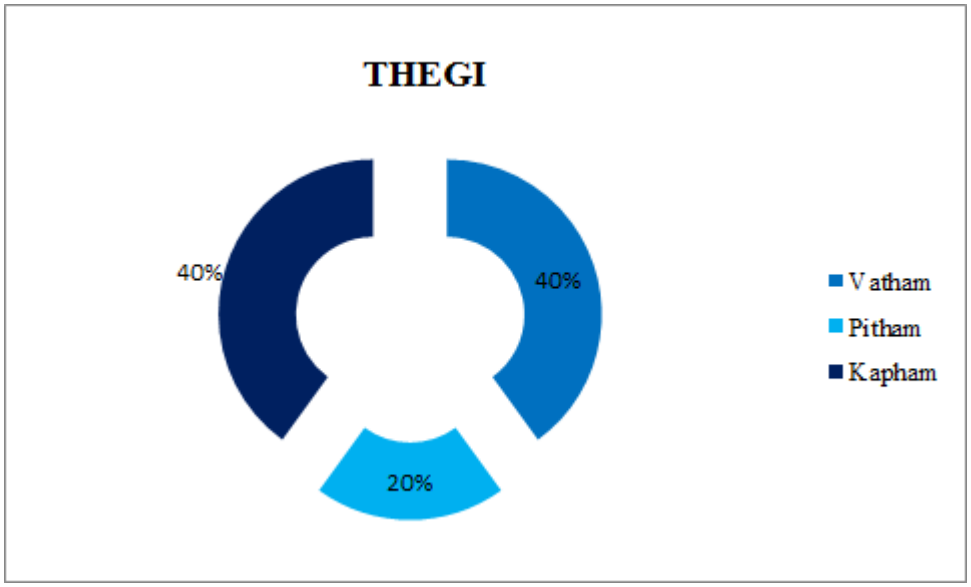
14. THEGI

Table: 14

Thegi	No of cases	Percentage
Vatham	16	40 %
Pitham	8	20 %
Kapham	16	40 %
Total	40	100 %

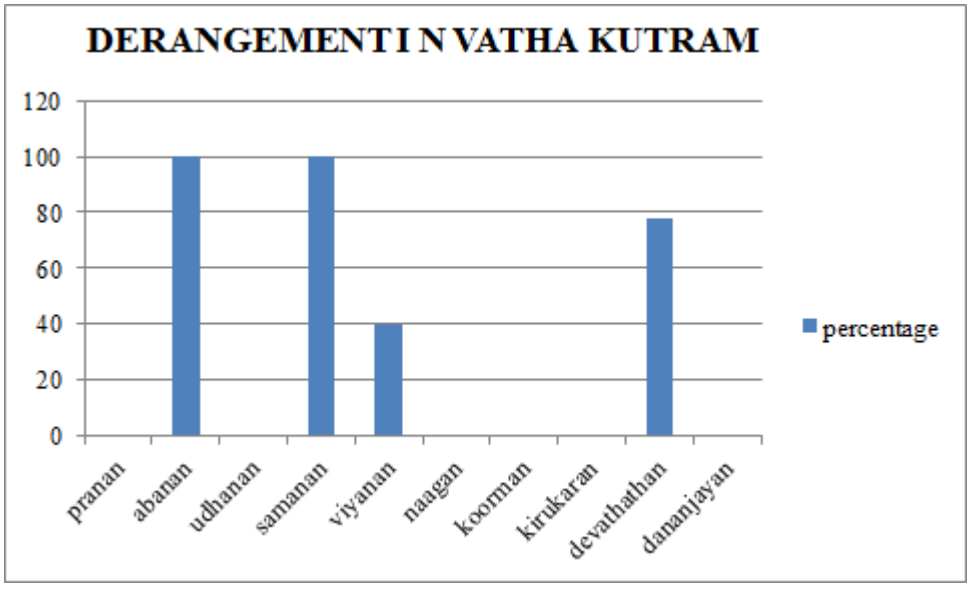


Observation: In the study, 16 cases(40%) were Vatha thegi, 16 cases(40 %) were Kapha thegi and another 8 cases(20 %) were Pitha thegi.

15. DERANGEMENT OF MUKKUTRAM

15. a. DERANGEMENT IN VATHAM: Table:

SI.No	Classification of vatham	No of cases	Percentage
1	Praanan	0	0 %
2	Abaanan	40	100 %
3	Udhaanan	0	0 %
4	Samaanan	40	100 %
5	Viyaanan	16	40 %
6	Naagan	0	0 %
7	Koorman	0	0 %
8	Kirukaran	0	0 %
9	Devathathan	31	77.5 %
10	Dananjayan	--	--



Observation: Abanan and Samanan were affected in all the 40 Patients(100%). In 31 cases (77.5%) Devathathan was affected, Viyanan was affected in 16 cases(40%)

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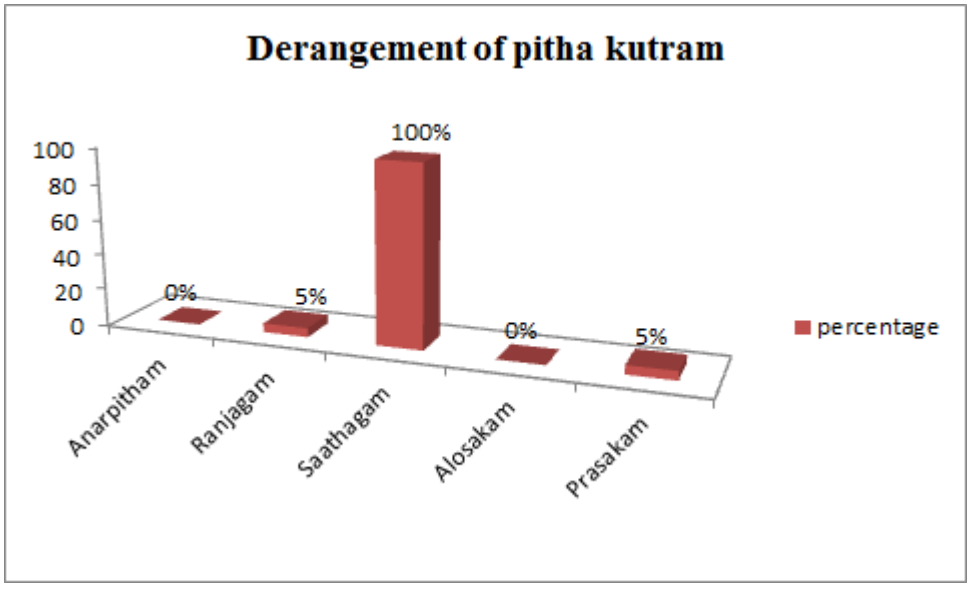
15. b. DERANGEMENTS IN PITHA KUTRAM:

Table: 15. b

SI.No	Classification of Pitham	No of cases	Percentage
1	Anarpitham	0	0 %
2	Ranjagam	2	5 %
3	Saathagam	40	100 %
4	Alosskam	0	0 %
5	Prasakam	2	5 %

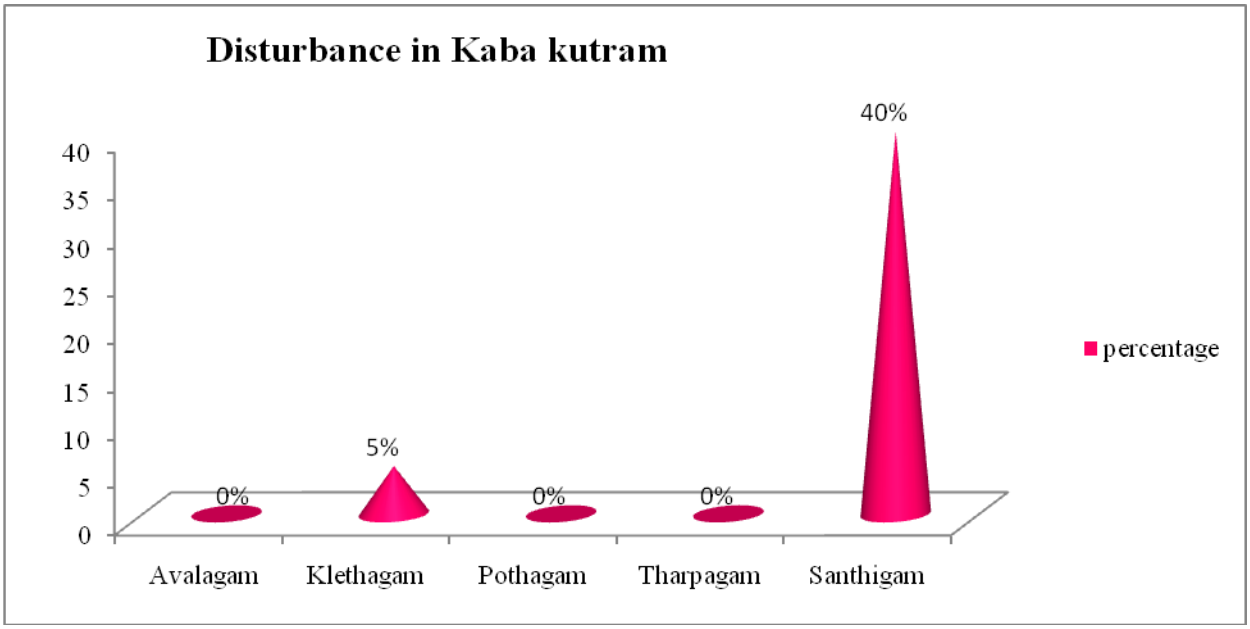


Observation: Among the 40 cases, Sathagam was affected in 40 cases(100%). Ranjagam was affected in 2 cases(5%) and Prasagam was affected in 2 cases(5%).

15.c DISTURBANCES IN KABA KUTRAM:

Table: 15.c

SI.No	Classification of Kabam	No of cases	Percentage
1	Avalambagam	0	0 %
2	Kelethagam	2	5 %
3	Pothagam	0	0 %
4	Tharpagam	0	0 %
5	Santhigam	16	40 %

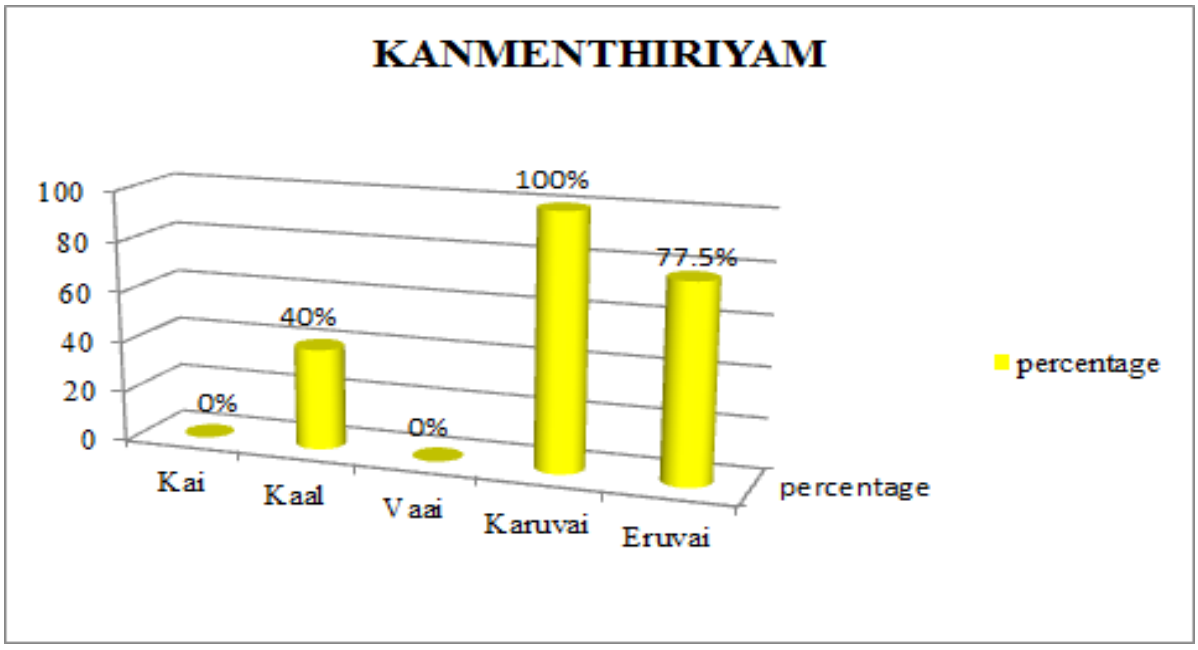


Observation: Among 40 cases, Santhigam was affected in 16 cases(40%) and Klethagam was affected in 2 cases(5 %) .

16. KANMENTHIRIYAM INVOLVEMENT:

Table: 16

Kanmenthiriyam	**No of cases**	**Percentage**
Kai	0	0 %
Kaal	16	40 %
Vaai	0	0 %
Karuvaai	40	100 %
Eruvaai	31	77.5 %



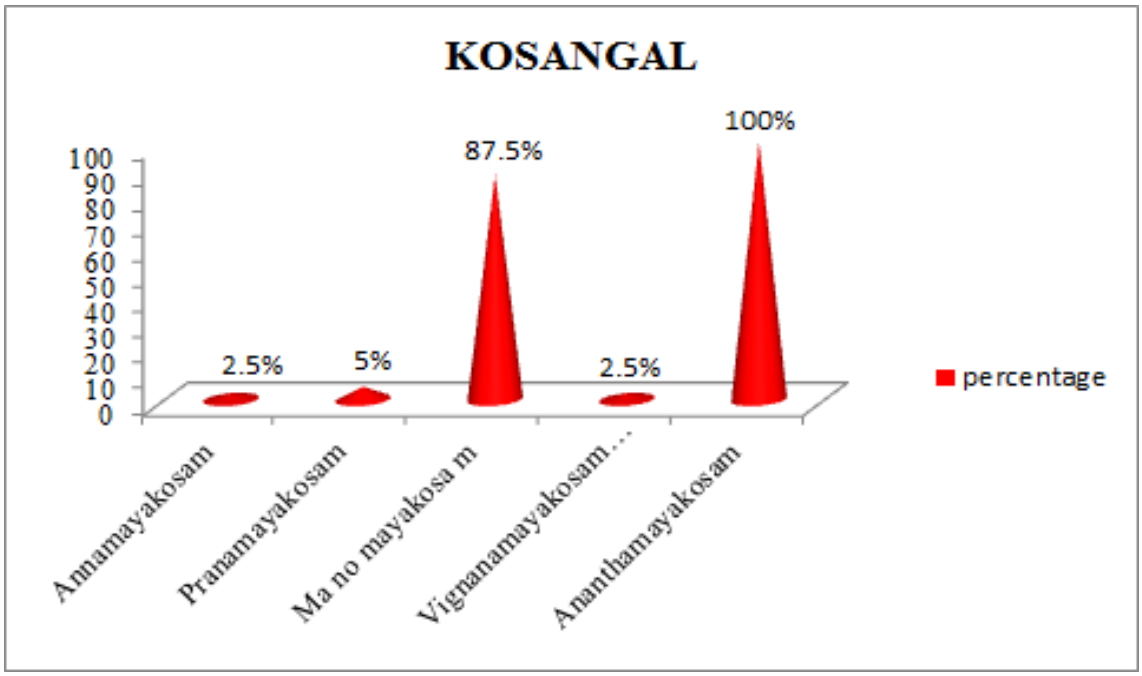
Observation:

Among the 40 cases, Karuvaai was affected in all 40 cases(100%) . Eruvaai was affected in 31 cases(77.5 %) and Kal was affected in 16 cases(40%).

17. KOSANGAL:

Table: 17

Kosam	No of cases	Percentage
Annamaya kosam	1	2.5 %
Pranamaya kosam	2	5 %
Manomaya kosam	35	87.5 %
Vignanamaya kosam	1	2.5 %
Anandamaya kosam	40	100 %

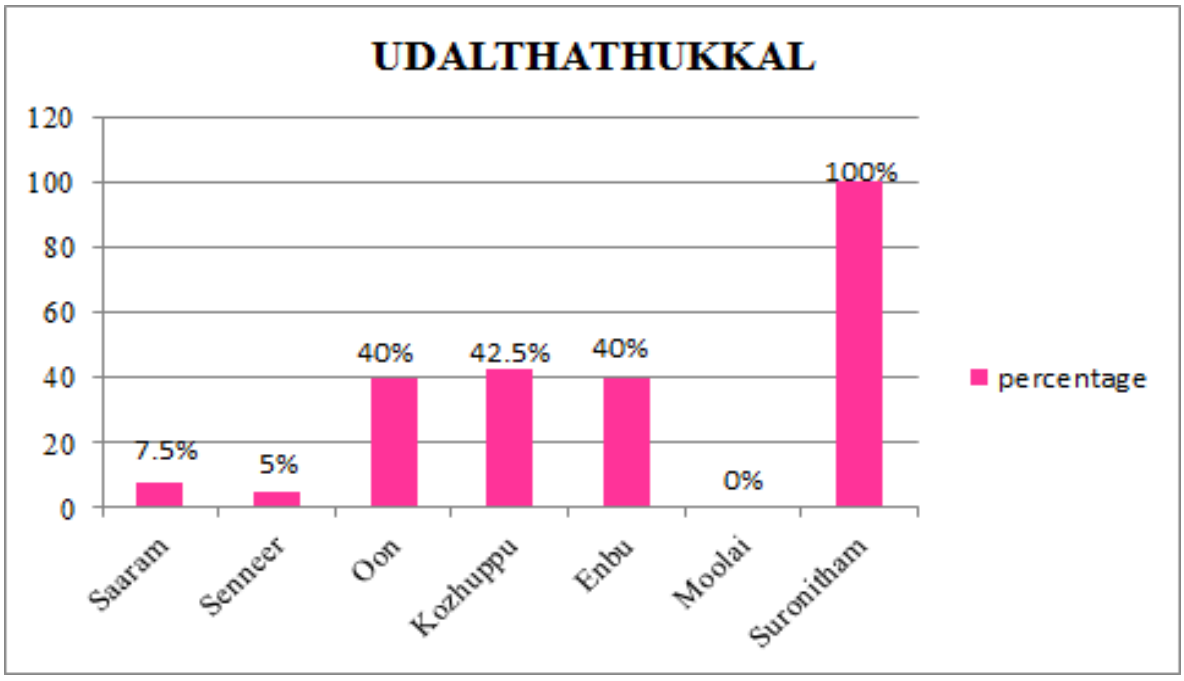


OBSERVATION: Among the 40 cases, all the 40 cases (100%) Ananthamaya kosam was affected, in 35 cases(87.5%) Manomaya kosam was affected and Vignanamaya kosam was affected in 1 cases(2.5%) .

18. DISTURBANCE IN UDAL THATHUKKAL

Table: 18

Udal Kattugal	No of cases	Percentage
Saaram	3	7.5 %
Senneer	2	5 %
Oon	16	40 %
Kozhuppu	17	42.5 %
Enbu	16	40 %
Moolai	0	0 %
Sukkilam/ Suronitham	40	100 %

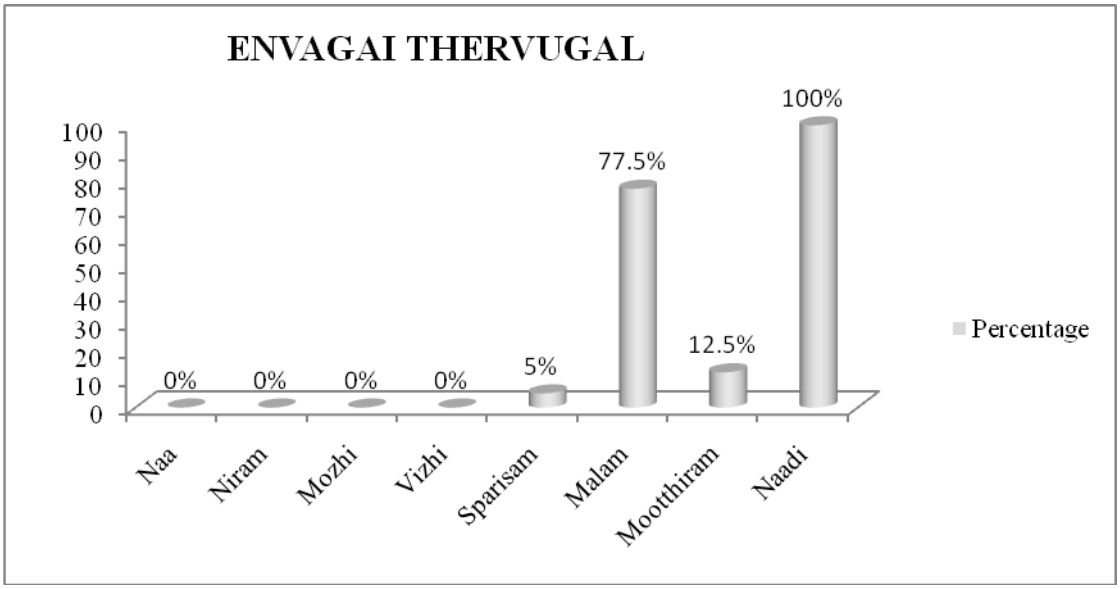


Observation: Among 40 cases, Suronitham was affected in all the 40 cases(100%) , Saaram was affected in 3 cases(7.5%) , Kozhuppu was affected in 17 cases(42.5%) and Oon was affected in 16 cases(40 %) , Enbu was affected in 16cases (40%) and Senneer was affected in 2 cases(5%).

19. ENVAGAI THERVUGAL (EIGHT DIAGNOSTIC METHODS)

Table 19

En Vagai Thervugal	No of cases	Percentage
Naa	0	0 %
Niram	0	0 %
Mozhi	0	0 %
Vizhi	0	0 %
Sparisam	2	5 %
Malam	31	77.5 %
Mothiram	5	12.5 %
Naadi (Thontham)	40	100 %

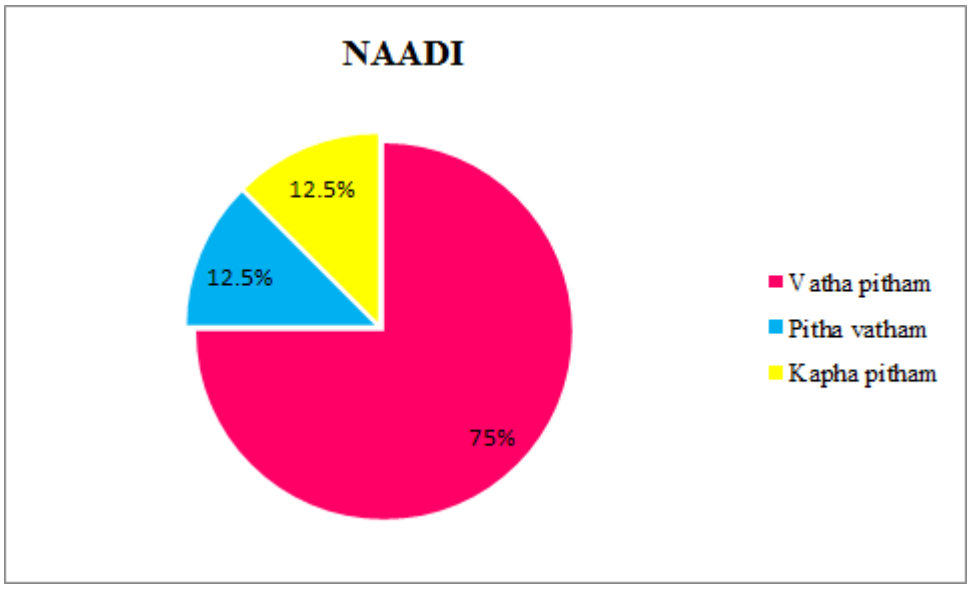


Observation: Malam was affected in 31 cases(77.5%) . Moothiram was affected in 5 cases(12.5%) , Sparisam was affected in 2 cases (2%) . In all the cases, examination of Naadi nadai revealed thontham.

19. a NAADI

Table: 19. a

Naadi	No of cases	Percentage
Vatha pittham	30	75 %
Pitha vatham	5	12.5 %
Kapha pittham	5	12.5 %
Total	40	100 %

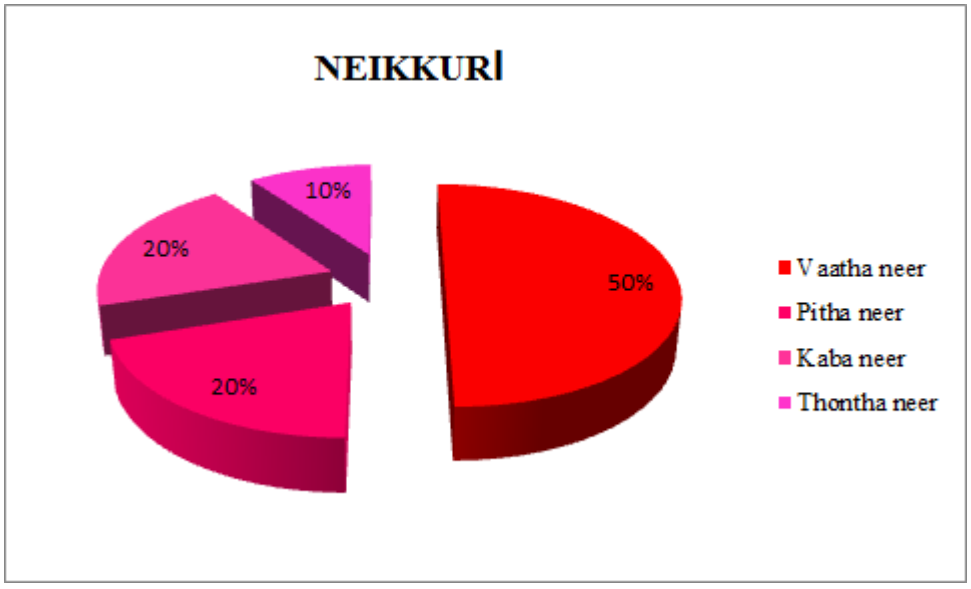


Observation: Majority of the cases 30 (75%) revealed Vatha Pitha naadi. 5 cases (12.5%) show Pitha vatham and 5 of the cases (12.5%) showed Pitha kaba naadi

19. b NEIKKURI (Oil on urine sign)

Table: 19. b

Types	No of cases	Percentage
Aravenaneendathu Vathaneer (Spreading like a snake)	**20**	**50 %**
Aazhipolparaviathu Pitha neer (Spreading like a ring)	**8**	**20 %**
Muththothu Ninrathu Kabaneer (Stands like a pearl)	**8**	**20 %**
Thontha neer	**4**	**10 %**
Total	**40**	**100 %**

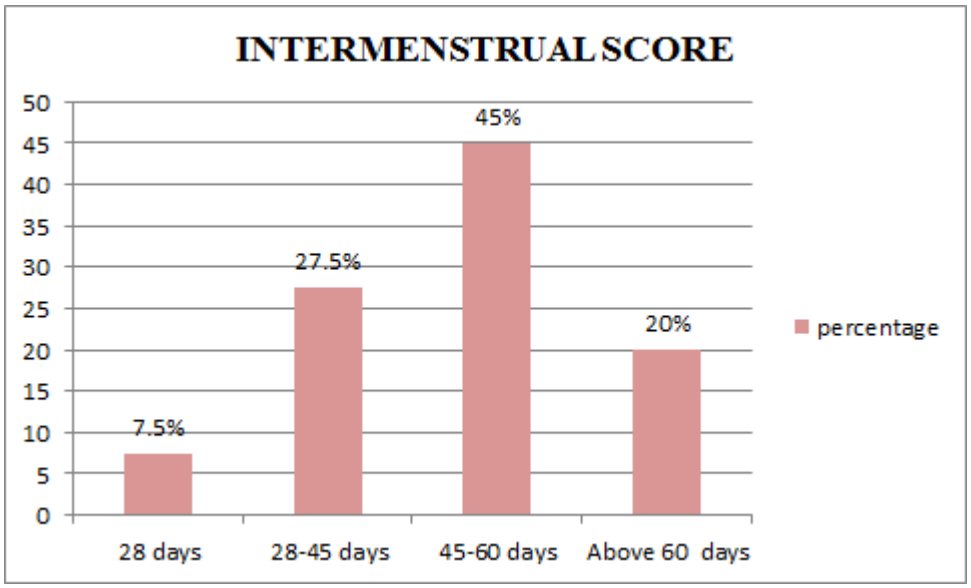


Observation: Among the 40 cases, 20 cases(50%) had Vatha neer, 8 cases(20%) had Pitha neer, 8 cases (20%) had Kabha neer and 4 cases (10%) had Thonta neer.

20. BEFORE TREATMENT ASSESSMENTS

20. a. INTER MENSTRUAL PERIOD ASSESSMENT SCORE

GRADE			BEFORE TREATMENT	
LENGTH OF CYCLE			Cases	Percentage
0	28 days	Nil	3	7.5%
1	28 – 45 days	Mild	11	27.5 %
2	45 – 60 days	Moderate	18	45 %
3	Above 60 days	Severe	8	20 %
	Total		40	100 %

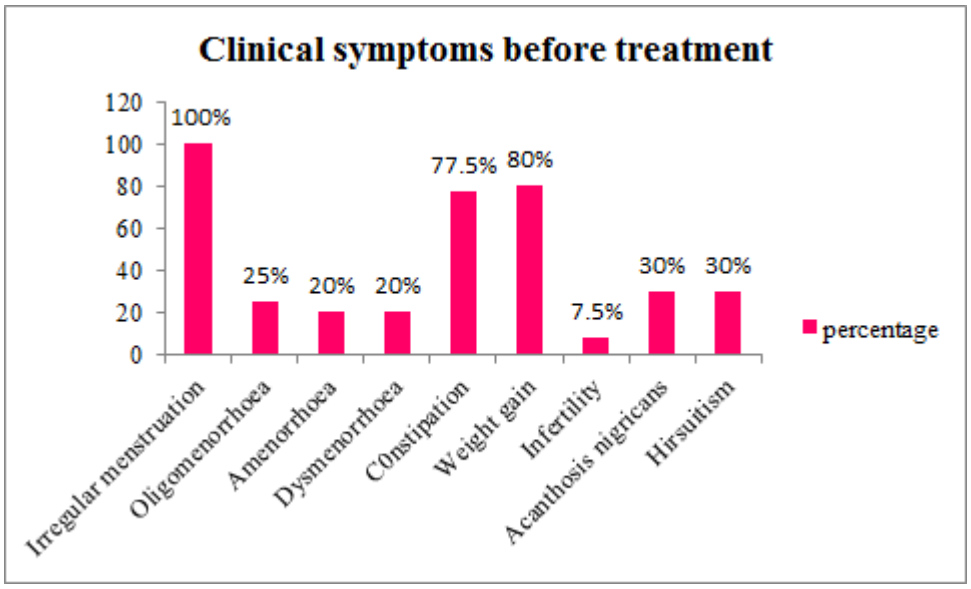


Observation: Among the 40 cases, 3 cases(7.5%) had 28 days cycle, 11 cases(27.5%) had 28-45 days cycle, 18 cases (45 %) had 45-60 days cycle and 8 cases (20 %) had above 60 days cycle.

20.b CLINICAL SYMPTOMS BEFORE TREATMENT:

Table: 20.c

Clinical symptoms	No of cases	Percentage
Irregular menstruation	40	100 %
Oligomenorrhoea	10	25 %
Amenorrhoea	8	20 %
Dysmenorrhoea	8	20 %
Constipation	31	77.5 %
Weight gain	32	80 %
Infertility	3	7.5 %
Acanthosis nigricans	12	30 %
Hirsuitism	12	30 %



Observation:

Out of the 40 cases, all 40 cases(100%) had irregular menstrual cycle (IMP or Duration of bleeding).

Weight gain was found in 32 cases (80 %), Constipation was seen in 31 cases(77.5 %)

Acanthosis nigricans was found in 12cases (30 %),

Hirsuitism had 12 cases (30 %) , 8 cases (20%) had amenorrhoea, 8 cases(20 %) had dysmenorrhea,

10 cases(25%) had oligomenorrhoea and 3 cases (7.5 %) had infertility.

RESULTS

RESULTS

21. OUTCOME MEASUREMENTS:

Out of 45 cases, 5 cases with drawn from the study due to long term absence. So the outcome was given for 40 cases before and after treatment.

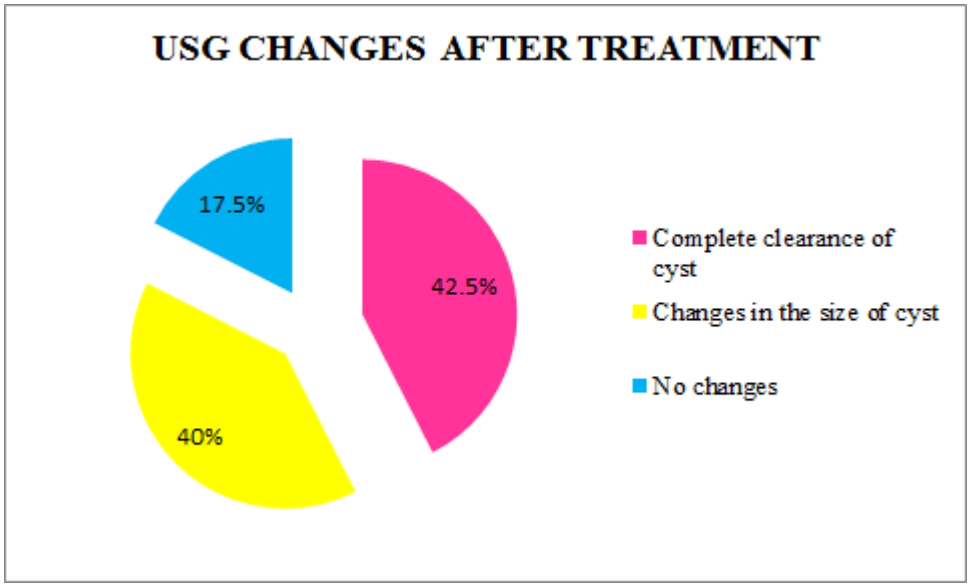
21.a ULTRASONOGRAPHY REPORT IN BEFORE AND AFTER TREATMENT

S.NO	OPD NO	NAME	AGE	BEFORE TREATMENT	AFTER TREATMENT
1	G91843	Mangaiyarkarasi	21	B/L POLYCYSTIC OVARIES	NORMAL STUDY
2	G99429	Sharly louisa	25	B/L POLYCYSTIC OVARIES	NORMAL STUDY
3	H00862	Nandhini	23	B/L POLYCYSTIC OVARIES	NORMAL STUDY
4	G92647	B.Anitha	30	B/L POLYCYSTIC OVARIES	NORMAL STUDY
5	H08939	Abarna	30	B/L POLYCYSTIC OVARIES	B/L POLYCYSTIC OVARIES
6	G93856	Anandhi	23	LEFT CYSTIC OVARY	NORMAL STUDY
7	H08424	Sudha	24	B/L POLYCYSTIC OVARIES	B/L POLYCYSTIC OVARIES
8	H08496	Aswathy	27	B/L POLYCYSTIC OVARIES	B/L POLYCYSTIC OVARIES
9	H01889	Mageshwari	28	B/L POLYCYSTIC OVARIES	NORMAL STUDY,
10	H13948	Benazir	23	B/L POLYCYSTIC OVARIES	B/L POLYCYSTIC OVARIES
11	H14793	Suganthi	21	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
12	H15049	Chitra	36	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
13	H16320	Shakila banu	29	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
14	H16297	Deepa	20	B/L POLYCYSTIC OVARIES	NORMAL STUDY
15	H08207	Thenmozhi	29	B/L POLYCYSTIC OVARIES BULKY UTERUS	NORMAL STUDY
16	H19521	S.Pavithra	23	B/L POLYCYSTIC OVARIES	B/L POLYCYSTIC OVARIES
17	G49654	Thulasi	29	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
18	H08313	Rathika	26	B/L POLYCYSTIC OVARIES	NORMAL STUDY
19	H07725	Amudhavalli	28	B/L POLYCYSTIC OVARIES	B/L POLYCYSTIC OVARIES
20	H16246	Suriyakala	32	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
21	G97934	Ranjitham	25	B/L POLYCYSTIC OVARIES	NORMAL STUDY
22	H26029	Geetha	32	RIGHT CYSTIC OVARY	NORMAL STUDY
23	H25763	P.Pavithra	20	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
24	H26007	Kasthuri	21	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
25	H28179	Sandhiya	24	LEFT CYSTIC OVARY	NORMAL STUDY
26	H05923	Mohanalakshmi	21	B/L POLYCYSTIC OVARIES	NORMAL STUDY
27	H28333	Suguna	23	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
28	H31190	Sadhana	28	B/L POLYCYSTIC OVARIES	B/L POLYCYSTIC OVARIES
29	H19738	V.Anandhi	26	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
30	H08744	J.Anitha	28	B/L POLYCYSTIC OVARIES	NORMAL STUDY
31	H30678	Akila	23	LEFT CYSTIC OVARY	REDUCED SIZE OF CYST
32	H24781	Preetha	20	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
33	H30919	S.Janani	26	B/L POLYCYSTIC OVARIES	NORMAL STUDY
34	G91734	Kanimozhi	23	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
35	G96488	Saraswathy	31	B/L POLYCYSTIC OVARIES	NORMAL STUDY
36	H35170	R.Janani	26	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
37	H27777	Gayathri	28	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
38	H20486	Sapna	24	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST
39	H36263	Vidhya	30	B/L POLYCYSTIC OVARIES	NORMAL STUDY
40	H00601	Keerthana	22	B/L POLYCYSTIC OVARIES	REDUCED SIZE OF CYST

21.a CHANGES IN USG ABDOMEN AFTER TREATMENT:

Table:21.a

IMPROVEMENT	USG ABDOMEN CHANGES	NO. OF CASES	PERCENT AGE
GOOD	Complete clearance of cyst	17	42.5 %
MODERATE	Changes in the size of the cyst	16	40 %
POOR	No changes in the size of the cyst	7	17.5 %
	TOTAL	**40**	**100 %**



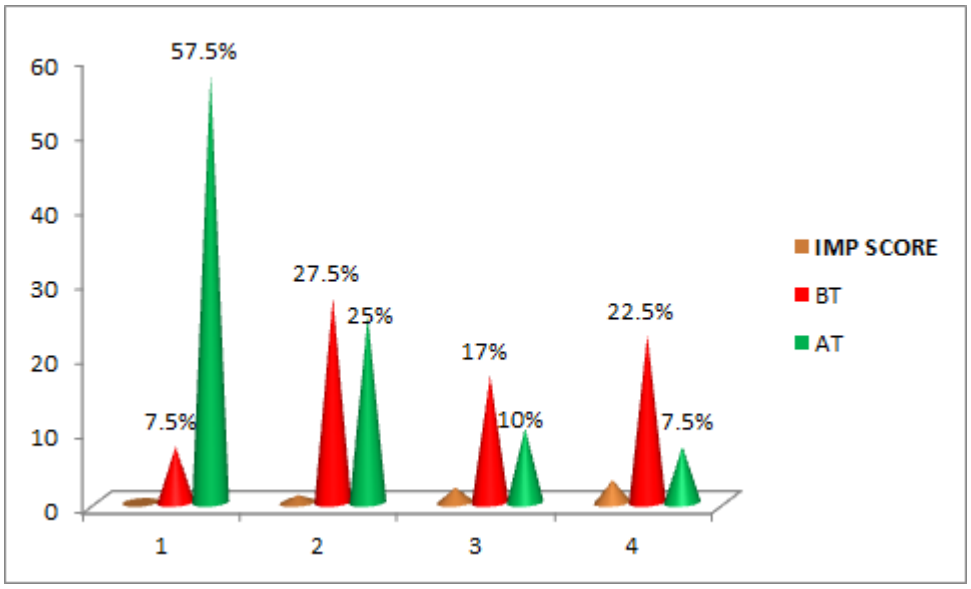
Observation: Out of 40 patients, All 40 cases show polycystic changes in both ovaries Out of which, 17 patients (42.5%) showed complete clearance of cyst after treatment. Moderate changes seen in 16 (40%) case. No significant improvements were seen in the remaining 7 (17.5%) cases**.**

21.b INTERMENSTRUAL SCORE IN BEFORE AND AFTER TREATMENT

S.NO	OPD NO	AGE	IMP SCORE	
			BEFORE TREATMENT	AFTER TREATMENT
1	G91843	21	2	0
2	G99429	25	2	0
3	H00862	23	1	0
4	G92647	30	1	0
5	H08939	30	3	2
6	G93856	23	0	0
7	H08424	24	1	0
8	H08496	27	1	0
9	H01889	28	1	0
10	H13948	23	2	1
11	H14793	21	3	2
12	H15049	36	0	0
13	H16320	29	2	1
14	H16297	20	3	1
15	H08207	29	0	0
16	H19521	23	3	3
17	G49654	29	2	0
18	H08313	26	1	0
19	H07725	28	3	3
20	H16246	32	1	0
21	G97934	25	2	0
22	H26029	32	3	0
23	H25763	20	2	1
24	H26007	21	2	1
25	H28179	24	1	0
26	H05923	21	2	0
27	H28333	23	2	1
28	H31190	28	2	1
29	H19738	26	2	0
30	H08744	28	2	0
31	H30678	23	2	1
32	H24781	20	1	0
33	H30919	26	1	0
34	G91734	23	3	3
35	G96488	31	2	1
36	H35170	26	2	1
37	H27777	28	2	2
38	H20486	24	3	0
39	H36263	30	1	0
40	H00601	22	3	2

21.b) INTER MENSTRUAL PERIOD ASSESSMENT SCORE

GRADE			BEFORE TREATMENT		AFTER TREATMENT		
LENGTH OF CYCLE			Cases	Percentage	Grade	Cases	Percentage
0	28 days	Nil	3	7.5 %	0	23	57.5 %
1	28 – 45 days	Mild	11	27.5 %	1	10	25 %
2	45 – 60 days	Moderate	17	42.5 %	2	4	10 %
3	Above 60 days	Severe	9	22.5 %	3	3	7.5 %
	Total		40	100 %	Total	40	100 %



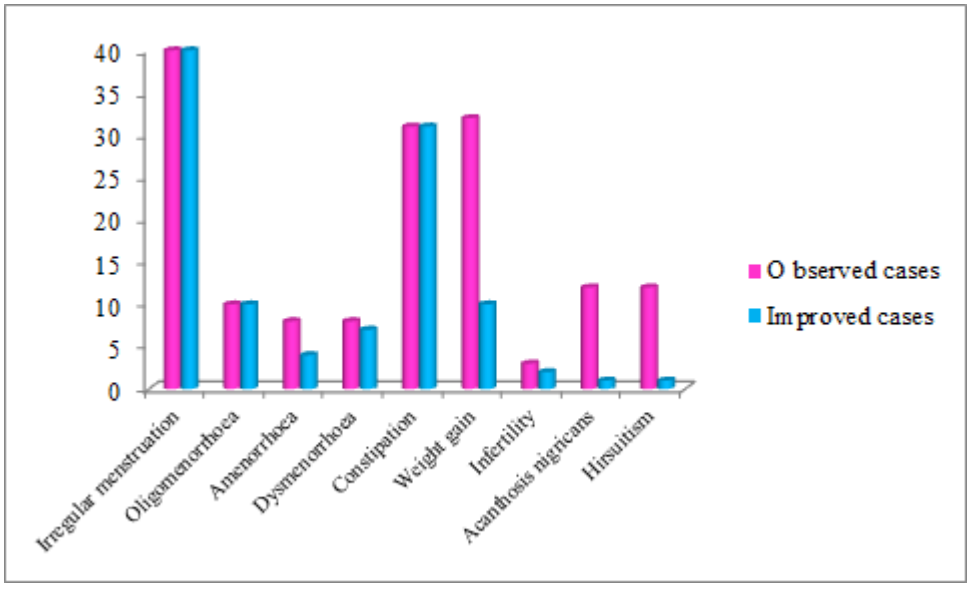
Observation:

Intermenstrual periods were found to be normal in 3 (7.5) patients and severe in 9 (22.5 %) cases before treatment. At the end of the treatment it was found normal in 23 (57.5%) number of cases and the severity was present only in 3 (7.5 %) case.

22. CLINICAL SYMPTOMS AFTER TREATMENT:

Table: 22

Clinical symptoms	No of cases observed	No of cases improved	Percentage
Irregular menstruation	40	40	100 %
Oligomenorrhoea	10	10	100 %
Amenorrhoea	8	4	50 %
Dysmenorrhoea	8	7	87.5 %
Constipation	31	31	100 %
Weight gain	32	10	31.25 %
Infertility	3	2	66.6 %
Acanthosis nigricans	12	1	8.3 %
Hirsuitism	12	1	8.3 %



Observation: Out of the 40 cases, all the 40 cases the menstrual cycle was irregular (IMP or Duration of bleeding) before treatment. Secondly, weight gain was found in (80 %) large number of patients before treatment.

After treatment there was a considerable reduction in all symptoms particularly irregular menstruation, oligomenorrhoea, Dysmenorrhoea and amenorrhoea.

After treatment there was a complete relief in the symptom like constipation and There was changes in the body weight (31.25%). 2 infertility with PCOS patients normal study in USG abdomen and regularized menstrual cycle after treatment

23.BMI IN BEFORE AND AFTER TREATMENT

S.NO	OPD NO	AGE	BT	AT
1	G91843	21	17	17
2	G99429	25	25.5	25
3	H00862	23	31.5	30.5
4	G92647	30	31	30
5	H08939	30	30.4	30.5
6	G93856	23	28.5	28
7	H08424	24	22.9	22.8
8	H08496	27	25.4	25
9	H01889	28	27.8	26
10	H13948	23	33.4	33
11	H14793	21	26.3	25
12	H15049	36	32.1	32
13	H16320	29	34	34
14	H16297	20	34.2	34
15	H08207	29	26.3	26
16	H19521	23	28.2	26
17	G49654	29	30.1	30
18	H08313	26	25	25
19	H07725	28	28	28
20	H16246	32	28	28
21	G97934	25	33.8	30.8
22	H26029	32	28	27
23	H25763	20	25	25
24	H26007	21	35.5	34
25	H28179	24	30	30
26	H05923	21	42	40
27	H28333	23	26	26
28	H31190	28	29	29
29	H19738	26	32	30
30	H08744	28	26.8	24
31	H30678	23	25	25
32	H24781	20	24	24
33	H30919	26	36.9	35.8
34	G91734	23	25	25
35	G96488	31	28	28
36	H35170	26	32	32
37	H27777	28	31	31
38	H20486	24	32	33
39	H36263	30	25.5	25.4
40	H00601	22	25	25

STATISTICAL ANALYSIS:

1. INTERMENSTRUAL PERIOD (IMP) SCORE BEFORE AND AFTER TREATMENT

(IMP SCORE BT and AT)

Variable	No	Mean±Std	T value	P value
BT	40	1.8±0.88	9.39	P<0.0001
AT	40	0.675±0.94		

The mean± standard deviation of pain score at before and after treatment were 1.8±0.88 and0.675±0.94 (t= 9.39 p <0.001).The % of improvement i.e,Regular menstrual cycle is 63% from 1.8 to 0.675. Respectively which is statistically significant.

DISCUSSION

DISCUSSION

Advancement in the modern technology has enabled our present day society to exist in a world where the constant of hard work even moderate work is absolute and infashionable. Though the modern medicine has advanced in its development it still lacks proper medicine in some disease such as PCOS, Psoriasis, etc. The physical inactivity, sedentary life style, food habits, environment pollution have caused so many diseases, especially in women of child bearing age with menstrual abnormalities, one such abnormality is Garpa vaayu.

Garpa vaayu is a disease characterized by abdominal discomfort, dysmenorrhoea, low back ache, constipation, amenorrhea, and heaviness of thigh. It may be correlated with Polycystic Ovarian Disease of modern science.

The main aim of the study is to document the effectiveness of the siddha medicine "Garpa vaayu ilagam (Internal medicines)" in the management of Garpa vaayu (Polycystic ovarian syndrome).

The standardization of the trial drug and the safety of the trial drug were ensured during the study through physicochemical analysis.

The drug was prepared as per standard operating procedure mentioned in the protocol in Gunapadam laboratory of National Institute of Siddha after getting authentication of the raw drugs.

The standardization of trial drug was carried out in biochemistry lab of NIS and CSRI, Chennai respectively. It revealed the presence of effective minerals.

The clinical study was conducted with a well defined protocol and a proper proforma after the approval of the Institutional Ethical Committee (IEC NO: NIS/IEC/8-14/6-26-08-2014). Out of 91 cases reported at the OPD of Maruthuvam and Magalir & sool maruthuvam, 40 cases were selected for induction to the trial. Before enrollment into the trial the informed consent was obtained from the patients.

Treatment was mainly aimed at balancing the elevated humors and treating the disease through siddha line of treatment – Purgation and Internal medication.

The trial drug Garpavaayu ilagam was given for 7 days medicine – 7 days drug holiday i.e (Total duration of drug administration is 42 days for the study period of 3 months). Which is referred in the Siddha literature Vaithiya saarasangiragam.

For OP patients, they should visit the hospital once in 14 days. At each clinical visit clinical assessment was done and prognosis was noted.

Laboratory investigations and radiological investigation were done before and after the trial. All the patients were put under observation for 2 months follow up period without the trial drug treatment.

The observations are summarized below.

1. Distribution of cases by age:

Among 40 cases

18 cases (45%) were in the age group of 20-24 years

16 (40%) cases in the age group of 25-29 years

5 (12.5%) cases were in the age group of 30-34 years

1(2.5%) case were in the age group of 35-40 yrs.

Inference:

In this study the prevalence of the disease was found to be higher in 18 cases (45%) in the age group of 20-24 years. Many women who have PCOS are very frustrated with their lives and ignore the symptoms and do not try to treat themselves until it is too late.

2. Distribution of cases by marital status:

Among the 40 patients selected, Prevalence of the disease was found to be higher in married females i.e.24 cases (60%) and 16 (40%) cases are single.

Inference: PCOS is a very common disorder that many women first learn about while seeking the cause of their infertility.

3.Distribution of case by Parity:

Out of 40 cases, 67.5% (27 cases) were found to be Nulliparous, 25% (10 cases) for PCOS and for second child and 7.5% (3cases) were in Multiparous.

Inference: PCOS is a very common disorder that many women first learn about while seeking the cause of their infertility

4. Distribution of cases by religion:

Among 40 patients, 36 (90%) cases were Hindu, 2(5%) cases were christian and 2 (5%) cases were Muslim**.**

5. Distribution of cases by Paruvakaalam:

Out of 40 cases, 20 cases (50%) the treatment period was Munpani kaalam, 19 (47.5%) cases Pinpani kaalam and 1(2.5%) case koothirkaalam.

6. Distribution of cases by Thinai:

Out of 40 cases, 19 (47.5%) were from the land Kurinji, 16 (40%) were from Neithal, 4 (10%) cases were from Mullai and 1 (2.5%) case from Marutham.

7. Distribution of cases by Diet:

Among 40 patients, 38 (95%) cases were non vegetarian, and 2(5%) cases were vegetarian.

Inference:

In this study most of the patients were observed to be non vegetarians.

8. Case distribution:

All the 40 patients had PCOS. Among them 27 cases (24 single and 3 married women) ie., 67.5% were diagnosed as PCOS only, 3cases (3 married women ie., 7.5%) were PCOS with Maladu (1º infertility) and 10 cases were PCOS with kathalimaladu (seeking for second child ie., 25%).

9. Distribution of cases by body built:

Among the 40 cases, 16 (40%) cases were obese, 16 (40%) cases were of over weight, 7 (17.5%) cases were normal weight and 1(2.5%) case comes under weight.

Inference:

In this study most of the subjects are Obese and overweight. Obesity, particularly the abdominal phenotype, may be partly responsible for insulin resistance and associated hyperinsulinemia in women with PCOS. Therefore, obesity-related hyperinsulinemia may play a key role in favouring hyperandrogenism in these women. These obviously emphasize the role of obesity in the pathophysiology of PCOS.

10. Distribution of cases by Occupation:

Among the 40 patients the incidence were more in sedentary workers ie., 19 (47.5 %) cases, next in home working 10 (25%) cases, next in students 9 (22.5%) and finally in standing workers 2 (5%) cases.

Inference: In this study most of the patients are sedentary workers. The incidence appears to be increase due to change in life style and stress. Sedentary workers are distressed by both physical aspects and psychological aspects

11. Distribution of cases by positive familial history:

Among the 40 cases observed, Positive familial history was seen in only 2 (5%) of patients and the other 38 (95%) cases has no family history for the incidence of the disease.

12. Distribution of cases by chronicity of illness:

Among 40 patients

21 cases (52.5 %) the duration of illness was between 6months – 1 yr,

2 (5%) cases was less than 6 months

6(15%)cases were between 1-2 years

4 (10%) cases the duration was between 2-5 yrs

5 (12.5%) cases between 5-10 yrs

2 (5%) cases the duration was more than 10 years.

Inference: In this study majority of the subjects are between 6months-1year chronicity.

13.Treatment history:

Among the 3 Infertility patients, 1 (33.33%) case only underwent ovulation inductionand 2 (66.66%) cases had not taken any other treatment.

Among the 35 PCOS patients, 29 (82.85%) cases were not taken any treatment, 4 (11.42%) cases underwent menstruation induction and 2 (5.71%) cases were under oral hypoglycaemic drug.

14. Thegi:

In the study, 16 (40%) cases were Vatha thegi, 16 (40 %) cases were Kapha thegi and another 8 (20 %) cases were Pitha thegi.

Inference: In this study most of the cases were Vatha and Kabha thegi.

15. Condition of Mukkuttram:

15.a. Derangement in Vatha kutram:

Among the 40 cases,

Abanan was affected in 40 (100%) cases which resulted in irregular menstruation.

Samanan was affected in all 40 (100%) cases which resulted in irregular menstruation.

Viyanan was affected in 16 (40%) of cases which resulted in low back ache.

Devadhathan was affected in 31 (77.5%) cases, which resulted in Constipation and lethargy.

Pranan, Udhanan, Nagan, Koorman, Kirukaran and Dhananjeyan remained normal in all 40 cases.

15.b. Derangement in Pitha Kutram:

Among the 40 cases

Sathagam was affected in 40 (100%) cases which resulted in irregular menstruation.

Ranjagam was affected in 2 (5%) cases, which resulted in reduced level of Hb.

Prasagam was affected in 2 (5%) cases which resulted in hyperpigmentation of the skin. Anarpitham and Alosagam remained normal in all cases.

15.c. Derangement in Kabha kutram:

Among 40 cases, Santhigam was affected in 16 (40%) cases which resulted in low back ache.

Klethagam was affected in 2 (5 %) cases which is resulted in Abdomen discomfort and Belching. All others remained normal

16.Distribution of cases by Kanmendrium:

Among 40 cases,

Karuvai was affected in all 40 (100%) cases leading to irregular periods

Eruvai was affected in 31 (77.5%) cases leading to constipation.

Kal (Lower limb) was affected in 16 (40%) cases leading to pain in lower limb

Kai and Vai were normal in all the 40 (100%) patients.

17. KOSANGAL:

Among the 40 cases, In all cases Ananthamaya kosam was affected resulted in irregular periods.

In 35 (87.5%) cases Manomaya kosam was affected resulted in mental depression.

In 1 (2.5%) cases Vignanamaya kosam was affected resulted in pain in joints.

In 1 (2.5%) cases the Annamaya kosam was affected resulted in Abdomen discomfort.

In 2 (5%) cases the Pranamaya kosam was affected resulted in dyspnoea.

18. Distribution of cases by Udal thathukkal:

Among 40 cases,

Suronitham was affected in all the 40 (100%) cases resulted in irregular menstruation

Saaram was affected in 3 (7.5%) cases that produced the symptoms like lethargy and mental depression.

Kozhuppu was affected in 17 (42.5%) cases that produced the symptoms like increased body weight

Oon was affected in 16 (40 %) cases resulted in joint pain lower limbs.

Enbu was affected in 16(40%) cases resulted in low back ache and hair fall.

Senneer was affected in 2 (5%) cases that produced symptoms like loss of strength, skin manifestation,reduced level of Hb.

Moolai was not affected in all the case concerned to the disease.

19. Distribution of cases by Envagai thervugal:

Malam was affected in 31 (77.5%) cases resulted in constipation.

Moothiram was affected in 5 (12.5%) cases resulted in Itching and Burning micturition.

Sparisam was affected in 2 (2%) cases resulted in hyperpigmentation of skin.

In all cases the type of Naadi was thontha naadi

All other remained normal.

19.a. Distribution of cases by Naadi type:

All the 40 cases showed Thontha naadi.

Vadha pitha naadi was predominant in 30 (75%) cases.

Pitha Vatha naadi was found in 5 (12.5%) cases.

Pitha Kabham naadi was found in 5 (12.5%) case.

19.b. Distribution of cases by Neikuri:

Among 40 cases,

20 (50%) cases had Vatham pattern of Neikuri i.e. Aravenaneendathu (Spreading like a snake)

8 (20%) cases had Kapham pattern of Neikuri. i.e Muththothu Ninrathu (Stands like a pearl).

8 (20%) cases had Pitham pattern of Neikuri .i.e. Aazhipolparaviathu (Spreading like a ring)

4 (10%) cases had Thontha neer.

20. BEFORE TREATMENT ASSESMENT

20.a.Intermenstrual Period Assesment Score before treatment :

Among the 40 cases

3 (7.5%) cases had 28 days cycle

11 (27.5%) cases had 28-45 days cycle

18 (45 %) cases had 45-60 days cycle

8 (20 %) cases had above 60 days cycle.

Inference: In this study most of the patients i.e.18 (45%) cases fall under 60 days cycle.

20.b. Clinical symptoms before treatment:

Out of the 40 cases, all 40 (100%) cases had irregular menstrual cycle (IMP or Duration of bleeding).

Weight gain was found in 32 (80 %) cases , Constipation was seen in 31 (77.5 %) cases, Acanthosis nigricans was found in 12 (30 %),

Hirsuitism had 12 (30 %) , 8 (20%) cases had amenorrhoea, 8 (20 %) cases had dysmenorrhea,

10 (25%) cases had oligomenorrhoea and 3 (7.5 %) cases had infertility.

OUTCOME MEASURES:

PRIMARY OUTCOME OBSERVATIONS:

21.a CHANGES IN USG ABDOMEN BEFORE AND AFTER TREATMENT :

Out of 40 patients,

All 40 cases show polycystic changes in both ovaries

Out of which, 17 patients (42.5%) showed complete clearance of cyst after treatment.

Moderate changes seen in 16 (40%) case.

No significant improvements were seen in the remaining 7 (17.5%) cases**.**

21.b.INTERMENSTRUAL PERIOD ASSESMENT SCORE

Intermenstrual periods were found to be normal in 3 (7.5) patients and severe in 9 (22.5 %) cases before treatment.

At the end of the treatment it was found normal in 23 (57.5%) number of cases and the severity was present only in 3 (7.5 %) case.

SECONDARY OUTCOME OBSERVATIONS:

CLINICAL SYMPTOMS:

22. Observation with reference to other Clinical symptoms:

Out of the 40 cases, all the 40 cases the menstrual cycle was irregular (IMP or Duration of bleeding) before treatment.

Secondly, Out of 32 patients, weight gain was found in (80 %) large number of patients before treatment and about 10 cases there was moderate significant in BMI after treatment.

After treatment there was a considerable reduction in all symptoms particularly irregular menstruation, oligomenorrhoea, Dysmenorrhoea and amenorrhoea.

After treatment there was a complete relief in the symptom like constipation and There was changes in the body weight (31.25%).

Out of 3 infertility with PCOS patients, 2 patients were reported normal study in USG abdomen and regularized menstrual cycle after treatment and one patient conceived after treatment.

STATISTICAL ANALYSIS:

BIO STATISTICAL ANALYSIS

The effectiveness of the clinical trial drug Garpa vaayu ilagam was assessed by using paired comparison test (paired t test). The responses (IMP) of the patients to the drug were analyzed.

Assessment of the effectiveness of drug:

The effectiveness of the drug was assessed by the improvement of the patients from irregular menstruation, which is measured using assessment score.

Inference: The test drug is statistically significant ($p>0.0001$) and hence effective in the treatment of Garpa vaayu

BIOCHEMICAL ANALYSIS:

Preliminary phytochemical analysis of Garpa vaayu ilagam (GVL) was done in NIS biochemical laboratory showed the presence of minerals like Calcium, chloride, Iron, Sugars, Alkaloid, Tannic acid, Unsaturated compound.

PHYSICOCHEMICAL ANALYSIS

1. pH% 5.6
2. Ash (%w/w) 3.33%
3. acid insoluble ash (%w/w) 0.48%
4. Loss on drying @105o C 11.77%
5. Water soluble extractive values 52.17%
6. Alcohol soluble extractive values 44.31%

SUMMARY

SUMMARY

- The aim of the study is to evaluate the therapeutic efficacy of siddha formulation Garpa vaayu ilagam (Internal medicine) in the management of Garpa vaayu (polycystic ovarian disease).

- The Study Protocol was approved by Institutional Ethical committee (IEC approval number: NIS/IEC/8-14/6-26-08-2014)

- Before initiating the clinical trial, it was registered in Clinical trial registry of India (CTRI- REF/2016/06/0111463)

- The raw drugs were authenticated by the Assistant professor of medicinal botany and the trial drug was prepared by the investigator in the Gunapadam laboratory of National Institute of Siddha.

- The qualitative and quantitative phytochemical studies were done at the bio chemistry laboratory of National Institute of Siddha and physio chemical analysis in SCRI Chennai.

- For the clinical study, 40 cases were recruited for the trial as per the inclusion and exclusion criteria and the informed consent was obtained from the patients. All these cases were treated in OPD of Ayothidoss pandithar hospital of NIS, Chennai.

- The trial medicine Garpavaayu ilagam 6gm was given in the morning for 7 days and next 7 days drug holiday for 3 months.

- Laboratory investigations were carried out before and after the treatment and the concerned data was recorded in the proforma.
- USG abdomen was also done before and after treatment.
- Clinical assessments were done once in 14 days in all the patients.

- During the study period, there was no adverse event reported.

- During the study period out of 45 cases 5 cases were withdrawn from the study due to long term absence.

- In this study out of 40 cases, the therapeutic efficacy of the trial drug by showing, USG report shows complete clearance of cyst in 17(42.5%) cases.

- Regular menstrual cycle ie., 28 days intermenstrual period in 23 (57.5%) cases.

- As per the Siddha Literature and recent research articles, the ingredients of the trial drug was found to have anti- oxidant, anti- diabetic, anti-hypercholesterolemia properties owing to the disease manifestations.

- Statistical analysis showed significant changes in the Intermenstrual period score before and after treatment.

- This ensures the safety usage of the drug as per the literature.

CONCLUSION

CONCLUSION

- Clinical study revealed the therapeutic efficacy of the trial drug by showing, regular menstrual cycle ie., 28 days intermenstrual period in 23 (57.5%) cases USG shows complete clearance of cyst in 17(42.5%) cases.

- No adverse drug reactions were noticed during the course of treatment.

- Expenditure of the trial drug is cost effective, easily preparable and highly effective in Garpa vaayu. Because of the encouraging clinical and laboratory results, the study may be undertaken with the same medicines for a prolonged period in a large number of cases for the treatment of Garpa vaayu.

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ANEXURES

LABORATORY REPORTS

HEMATOLOGY AND BIOCHEMISTRY REPORTS BEFORE AND AFTER TREATMENT

S.NO	OP.NO	Hbgms%		TC cells/Cumm		RBC 10^6Cells/cu.mm		ESR/hr	
		BT	AT	BT	AT	BT	AT	BT	AT
1	G91843	12.7	11.8	6700	5900	4.4	4.3	22	6
2	G99429	12.6	12.4	8000	8000	4.8	4.8	34	36
3	H00862	14	14.4	11900	8900	4.6	4.7	4	4
4	G92647	13.9	13.7	7660	8000	5.1	5	8	4
5	H08939	12.2	12.5	8800	10900	4.5	4.4	22	26
6	G93856	13.2	12.6	8000	9900	4.5	4.4	22	24
7	H08424	13.7	13.5	10600	8800	4.6	4.3	22	12
8	H08496	10.9	11	7400	6800	4.7	4.9	42	4
9	H01889	12.4	12.5	7800	8200	4.5	4.6	22	12
10	H13948	12	12.4	9600	8900	5.0	5.2	80	64
11	H14793	13.1	13	8300	7800	4.8	4.4	32	12
12	H15049	12.4	12.2	9600	10200	4.6	4.3	12	10
13	H16320	11.9	12	8800	8800	4.6	4.8	28	12
14	H16297	11.4	11.6	9800	9800	3.4	3.8	26	10
15	H08207	10.2	9.7	5900	5000	4.5	4.4	24	32
16	H19521	13.5	13.8	7100	7200	4.9	5.1	22	20
17	G49654	13.7	1 3.3	11000	10300	4.7	4.5	26	6
18	H08313	11.3	11.5	11200	10400	4.6	4.7	24	16
19	H07725	13.0	13.1	10800	10900	4.8	4.9	102	40
20	H16246	13.8	13.6	9500	6800	4.7	4.7	32	12

S.NO	OP.NO	Hbgms%		TC cells/Cumm		RBC 10^6Cells/cu.mm		ESR/hr	
		BT	AT	BT	AT	BT	AT	BT	AT
21	G97934	12.9	12.9	8700	7300	3.9	3.9	22	20
22	H26029	13	13	8900	9000	4.2	4.2	20	16
23	H25763	12.1	12.2	9200	7800	4.1	4.3	46	22
24	H26007	11	11	11100	11000	4.6	4,4	20	16
25	H28179	11.7	12	8600	8500	4.4	4.4	12	10
26	H05923	11.6	11.4	9200	9400	4.6	4.4	42	22
27	H28333	10.8	10.6	7700	8900	3.8	3.9	26	12
28	H31190	13.6	13.5	10000	10200	4.9	4.8	12	10
29	H19738	11.4	11.3	7000	7200	4.4	4.4	6	6
30	H08744	10.2	10.1	8700	10300	4.7	4.7	20	20
31	H30678	12.8	12.9	7100	8700	4.8	4.8	12	10
32	H24781	13.5	14	6200	8200	4.4	4.6	6	6
33	H30919	12.2	12.4	8200	8700	3.8	4.0	24	18
34	G91734	11.6	11.7	10300	10200	4.4	4.4	12	10
35	G97488	12.1	12	7400	8400	4.2	4.2	22	16
36	H35170	12.8	13	8500	8600	4.6	4.8	44	22
37	H27777	13.1	13	7100	7800	4.5	4.4	20	18
38	H20486	11.8	12.5	5800	6500	4.1	4.5	10	10
39	H36263	12.5	12.5	5600	7000	4.3	4.1	14	10
40	H00601	12	12	9100	9200	4.1	4.0	16	14

S.NO	OP.NO	Poly morphs %		Lymphocytes %		Mono Cytes %		Eosinophils %	
		BT	AT	BT	AT	BT	AT	BT	AT
1	G91843	73	67	23	27	1	2	3	4
2	G99429	51	57	43	37	2	1	4	5
3	H00862	60	59	35	36	1	1	4	4
4	G92647	61	60	35	36	1	1	3	3
5	H08939	52	57	44	37	0	1	4	5
6	G93856	58	72	37	23	1	1	4	4
7	H08424	68	57	25	37	2	2	5	4
8	H08496	58	59	38	35	2	2	4	4
9	H01889	65	68	31	26	1	2	3	4
10	H13948	70	61	24	33	2	2	4	4
11	H14793	72	62	22	31	2	1	4	6
12	H15049	65	70	30	26	1	1	4	3
13	H16320	60	60	37	36	0	1	4	4
14	H16297	62	61	35	35	0	1	3	3
15	H08207	51	40	43	52	2	0	4	8
16	H19521	59	60	36	35	1	1	4	4
17	G49654	68	70	27	2 4	1	1	4	5
18	H08313	70	67	26	29	1	1	3	3
19	H07725	62	61	34	32	1	1	4	6
20	H16246	72	60	24	34	1	1	3	5

S.NO	OP.NO	Poly morphs %		Lymphocytes %		Mono Cytes %		Eosinophils %	
		BT	AT	BT	AT	BT	AT	BT	AT
21	G97934	60	65	35	29	1	1	4	5
22	H26029	61	64	33	30	1	1	5	5
23	H25763	64	65	31	30	1	1	4	4
24	H26007	60	60	36	34	1	2	3	4
25	H28179	58	59	38	35	2	2	4	4
26	H05923	72	60	24	34	1	1	3	5
27	H28333	73	67	23	27	1	2	3	4
28	H31190	65	70	30	26	1	1	4	3
29	H19738	68	66	26	29	2	1	4	4
30	H08744	72	60	24	34	1	1	3	5
31	H30678	51	57	43	37	2	1	4	5
32	H24781	68	70	27	2 4	1	1	4	5
33	H24781	68	57	25	37	2	2	5	4
34	H30919	59	60	36	35	1	1	4	4
35	G96488	60	60	37	35	0	1	4	5
36	H35170	59	60	36	35	1	1	4	4
37	H27777	52	57	44	37	0	1	4	5
38	H20486	72	62	22	31	2	1	4	6
39	H36263	59	60	36	36	1	1	4	3
40	H00601	62	61	35	35	0	1	3	3

S.NO	OP.NO	Blood Sugar(F)		Blood Sugar(PP)	
		BT	AT	BT	AT
1	G91843	88	106	99	120
2	G99429	91	140	96	149
3	H00862	93	86	110	106
4	G92647	105	90	95	110
5	H08939	80	80	86	125
6	G93856	82	80	110	110
7	H08424	90	86	120	110
8	H08496	82	80	132	120
9	H01889	95	88	102	100
10	H13948	93	94	110	100
11	H14793	88	86	84	100
12	H15049	89	87	102	100
13	H16320	104	80	130	110
14	H16297	95	90	100	90
15	H08207	77	84	93	100
16	H19521	104	90	90	95
17	G49654	71	89	102	100
18	H08313	90	80	110	100
19	H07725	119	90	130	110
20	H16246	82	80	128	120

S.NO	OP.NO	Blood Sugar(F)		Blood Sugar(PP)	
		BT	AT	BT	AT
21	G97934	95	90	100	98
22	H26029	100	95	120	100
23	H25763	90	80	130	110
24	H26007	84	80	120	110
25	H28179	98	80	99	90
26	H05923	104	92	94	116
27	H28333	82	80	128	120
28	H31190	95	90	100	90
29	H19738	119	90	130	110
30	H08744	94	86	120	110
31	H30678	119	90	130	110
32	H24781	95	90	100	90
33	H24781	88	86	84	100
34	H30919	96	88	117	100
35	G96488	91	140	130	119
36	H35170	88	87	90	100
37	H27777	89	86	84	100
38	H20486	110	90	130	109
39	H36263	87	80	98	90
40	H00601	96	85	100	90

S.NO	OP.NO	Urea mg/dl		Creatinine mg/dl		Uric Acid mg/dl	
		BT	AT	BT	AT	BT	AT
1	G91843	12	0.8	18	0.9	2.8	2.1
2	G99429	18	16	0.8	0.8	4.6	4.6
3	H00862	07	18	0.7	0.8	6.2	5.5
4	H08939	18	28	0.9	0.9	6.5	6.3
5	G92647	14	14	0.9	0.9	5.4	5.4
6	G93856	15	14	0.9	0.8	2.9	3.3
7	H08424	13	14	1.0	0.8	2.1	2.9
8	H08496	17	14	0.9	1.0	3.4	4.7
9	H01889	13	16	0.9	0.8	2.2	4.5
10	H13948	16	17	1.7	0.9	3.7	4.2
11	H14793	19	27	1.3	0.7	5.4	4.8
12	H15049	20	24	0.8	0.8	4.9	4.9
13	H16320	20	24	0.8	0.8	4.8	4.8
14	H16297	18	18	0.8	0.8	4.8	4.8
15	H08207	16	17	0.7	0.7	3.5	3.7
16	H19521	10	10	0.7	0.7	3.9	3.9
17	G49654	17	16	0.9	0.9	4.0	4.0
18	H08313	20	28	1.0	1.0	4.1	4.6
19	H07725	19	19	0.9	0.9	5.3	5.0
20	H16246	17	12	1.0	0.8	3.1	3.7

S.NO	OP.NO	Urea mg/dl		Creatinine mg/dl		Uric Acid mg/dl	
		BT	AT	BT	AT	BT	AT
21	G97934	13	19	0.9	0.7	4.7	5.5
22	H26029	14	14	0.8	0.8	4.8	4.6
23	H25763	15	13	0.9	0.9	5.0	4.8
24	H26007	11	16	0.9	0.8	4.2	5.1
25	H28179	26	24	0.9	0.9	3.5	3.8
26	H05923	19	21	0.9	0.9	3.7	3.7
27	H28333	13	16	0.8	0.8	3.7	3.8
28	H31190	13	15	0.6	0.6	3.1	3.5
29	H19738	18	24	0.7	0.9	3.5	3.3
30	H08744	18	24	0.8	0.8	2.2	2.2
31	H30678	18	20	0.7	0.7	3.5	3.2
32	H24781	25	24	0.9	0.8	3.5	3.8
33	H24781	12	10	0.7	0.7	3.9	3.9
34	H30919	28	24	1.0	1.0	4.1	4.6
35	G96488	15	17	0.7	0.7	6.2	6.0
36	H35170	21	18	0.7	0.8	4.8	4.8
37	H27777	19	18	0.7	0.7	3.4	3.3
38	H20486	14	20	0.6	0.7	4.5	4.5
39	H36263	11	16	0.8	0.9	2.9	2.8
40	H00601	16	14	0.7	0.6	4.2	4.1

S.NO	OP.NO	Total Bilirubin mg/dl		Direct Bilirubin mg/dl		Indirect Bilirubin mg/dl		SGOT IU		SGPT IU		Alk.phos mg/dl	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	G91843	0.6	1.0	0.3	0.5	0.3	0.5	16	20	07	22	43	43
2	G99429	0.4	0.5	0.2	0.2	0.2	0.3	14	19	16	20	111	93
3	H00862	0.4	0.3	0.2	0.0	0.2	0.3	19	21	14	11	98	72
4	H08939	0.4	0.6	0.2	0.2	0.2	0.4	26	14	32	16	53	50
5	G92647	0.4	0.4	0.2	0.2	0.2	0.2	22	22	25	22	113	100
6	G93856	0.4	0.6	0.2	0.2	0.2	0.4	31	32	44	42	69	59
7	H08424	0.4	0.6	0.2	0.3	0.2	0.3	23	13	19	08	66	54
8	H08496	0.2	0.3	0.1	0.1	0.1	0.2	16	19	08	16	56	61
9	H01889	0.7	1.1	0.3	0.4	0.4	0.7	18	20	14	20	58	53
10	H13948	0.5	0.4	0.2	0.1	0.3	0.3	18	19	18	19	79	86
11	H14793	0.3	0.3	0.1	0.1	0.2	0.2	17	33	16	41	69	75
12	H15049	0.6	0.4	0.2	0.2	0.4	0.2	15	14	4	4	48	41
13	H16320	0.4	0.4	0.2	0.2	0.2	0.2	17	17	16	14	79	80
14	H16297	0.3	0.3	0.1	0.1	0.2	0.2	21	20	15	14	102	100
15	H08207	0.4	0.5	0.2	0.2	0.2	0.3	17	21	20	19	61	50
16	H19521	0.4	0.4	0.2	0.2	0.2	0.2	20	21	20	15	102	100
17	G49654	0.3	0.2	0.1	0.1	0.2	0.1	17	23	14	26	91	111
18	H08313	0.8	0.6	0.4	0.3	0.4	0.3	13	15	03	10	81	81
19	H07725	0.4	0.4	0.2	0.2	0.2	0.2	21	22	12	10	91	92
20	H16246	0.5	0.5	0.2	0.2	0.3	0.3	16	20	07	17	71	65

S.NO	OP.NO	Total Bilirubin mg/dl		Direct Bilirubin mg/dl		Indirect Bilirubin mg/dl		SGOT IU		SGPT IU		Alk.phos mg/dl	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	G97934	0.8	0.8	0.3	0.3	0.5	0.5	18	17	18	25	69	78
22	H26029	0.4	0.5	0.2	0.2	0.2	0.3	14	19	16	20	111	93
23	H25763	0.8	0.5	0.4	0.2	0.4	0.3	18	21	24	13	63	66
24	H26007	0.3	0.6	0.1	0.2	0.2	0.4	17	14	24	16	69	50
25	H28179	0.4	0.4	0.2	0.2	0.2	0.2	13	20	10	16	56	50
26	H05923	0.3	0.6	0.2	0.2	0.1	0.4	13	23	07	10	64	59
27	H28333	0.6	0.6	0.3	0.3	0.3	0.3	17	13	13	08	102	84
28	H31190	0.7	0.3	0.3	0.1	0.4	0.2	14	19	16	16	105	81
29	H19738	0.3	1.1	0.2	0.4	0.1	0.7	17	20	18	20	61	53
30	H08744	0.3	0.4	0.1	0.2	0.2	0.2	14	15	12	9	90	87
31	H30678	1.0	0.3	0.5	0.1	0.5	0.2	23	33	17	41	90	75
32	H24781	0.7	0.4	0.3	0.2	0.4	0.2	28	14	26	24	66	41
33	H30919	0.8	0.4	0.3	0.2	0.5	0.2	23	17	69	58	81	80
34	G91734	0.4	0.3	0.1	0.1	0.3	0.2	28	20	35	14	98	90
35	G96488	0.5	0.5	0.2	0.2	0.3	0.3	21	21	36	18	64	50
36	H35170	0.3	0.4	0.1	0.2	0.2	0.2	14	21	12	15	28	46
37	H27777	0.3	0.2	0.1	0.1	0.2	0.1	21	23	17	26	55	62
38	H20486	0.6	0.6	0.3	0.3	0.3	0.3	31	15	30	10	50	61
39	H36263	0.4	0.6	0.1	0.3	0.3	0.3	15	08	12	12	55	56
40	H00601	0.7	0.3	0.3	0.2	0.4	0.1	17	15	10	10	47	48

S.NO	OP.NO	Total cholestrol		HDL		LDL		VLDL		TGL	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	G91843	120	133	53	64	62	67	12	08	62	39
2	G99429	169	165	38	52	106	93	11	27	158	133
3	H00862	111	141	38	45	71	79	26	33	131	162
4	G92647	168	160	38	42	72	70	48	27	158	132
5	H08939	196	207	40	43	129	122	71	43	353	213
6	G93856	195	231	42	49	126	120	48	27	239	136
7	H08424	168	178	62	58	104	100	25	12	127	58
8	H08496	167	186	45	42	106	102	25	31	124	157
9	H01889	163	152	51	46	99	90	12	12	59	58
10	H13948	222	237	56	51	141	139	12	29	83	146
11	H14793	175	195	64	71	105	110	12	21	60	105
12	H15049	198	177	62	54	117	105	23	31	113	157
13	H16320	184	175	47	44	103	98	68	60	341	300
14	H16297	162	160	46	40	92	90	31	31	154	150
15	H08207	135	150	65	70	72	75	12	18	84	91
16	H19521	247	160	34	45	213	139	39	17	197	180
17	G49654	232	223	43	45	146	134	21	35	105	177
18	H08313	126	128	47	40	72	72	12	25	58	123
19	H07725	228	150	58	70	149	73	46	25	228	180
20	H16246	169	161	59	63	91	88	13	23	65	113

S.NO	OP.NO	Total cholestrol		HDL		LDL		VLDL		TGL	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	G97934	147	157	41	48	87	92	17	25	84	126
22	H26029	157	140	42	45	84	82	17	24	86	120
23	H25763	184	169	62	51	97	93	1 1	28	57	140
24	H26007	157	150	44	51	83	80	19	20	93	110
25	H28179	146	200	51	51	82	80	20	19	99	99
26	H05923	169	150	53	50	99	80	18	17	89	90
27	H28333	165	160	53	63	90	70	32	19	162	150
28	H31190	135	130	47	57	99	82	12	19	62	60
29	H19738	133	120	57	58	75	70	14	12	68	66
30	H08744	135	130	30	29	80	79	13	16	67	82
31	H30678	144	140	60	62	90	70	08	12	39	118
32	H24781	117	115	56	55	82	80	06	12	28	90
33	H24781	192	190	43	44	113	80	37	30	184	150
34	H30919	144	150	40	50	100	82	30	22	132	122
35	G96488	124	130	39	61	70	68	15	20	73	120
36	H35170	143	140	39	42	70	68	35	20	176	150
37	H27777	179	160	59	62	82	70	16	20	80	140
38	H20486	115	143	59	62	70	73	07	25	33	125
39	H36263	163	158	55	47	103	104	27	44	134	136
40	H00601	162	165	57	56	98	90	19	24	94	120

PROTOCOL

1.0 TITLE:

Clinical evaluation of siddha drug **Garpa vaayu ilagam** (internal)in the treatment of**Garpa vaayu (polycystic ovarian syndrome).**

Reg. no : Date of submission:

2.0 NAME OF THE INSTITUTION :

National institute of Siddha
Chennai-47
Telephone No : 044-22411611
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3.0 NAME OF THE RESEARCH SCHOLAR :

Dr.S.Shagila
P.G. Scholar, 1st Year[2014 – 2015],
Department of Maruthuvam,
National Institute of Siddha,
Chennai – 47.

4.0 NAME OF THE GUIDE:

Prof.Dr.S.MOHAN,.MD(S)
Director and Head of the Department,
Dept. of Maruthuvam
National Institute of Siddha,
Chennai -47.

6.0 OBJECTIVES

6.1 Primary Objective:

To study the therapeutic efficacy of siddha drug **"Garpa vaayu ilagam"** (Internal medicine) in the treatment of **Garpa vaayu** (polycystic ovarian syndrome) assessed through clearance of cysts in the ovary by USG abdomen and resumption of Regular menstrual cycle.

6.2 Secondary Objective:

- To study the comorbid factors related to the disease such as Irregular menstruation, Amenorrhoea, Oligomenorrhoea, Obesityetc...

7.0 STUDY DESIGN

Study type: An Open Clinical trial

Study Place: OPD & IPD Of theAyothidass Pandithar Hospital ,
National Institute of Siddha,
Tambaram sanatorium,
Chennai-47.

Study Period **:** 12 months

Sample size **:** 40 patients

8.0 TREATMENT

Drug **:** Garpavaayu ilagam

Dosage : Kottai pakkalavu (6gm), morning,before food

Duration : like wise 7days medicine -7 days drug holiday

Study period : 3months/ Patient

Total duration of drug administration : 42 days

Reference : Aathmarakshamirtham ennum Vaithiya saarasangiragam

Book : Pg-59, September 2011

Urai aasiriyar : Kanthasamy mudhaliyar.

Patthiyam(Dietry restriction) : Avoid Karapan inducing foods□ □ □ □

Note□ :Karapan inducing foods: Solam(Maize), Kambu(Pear milet), Varagu (Kodo millet), Kaar Arici(rice) , Vaazaikai(Unriped banana), Paagal(Bitter gourad), and kelitrumeen(fish).

9.0 STANDARD OPERATING PROCEDURE:

- The required raw drugs are purchased from a well reputed indigenous drug shop.
- The raw drugs will be authenticated by the Botanist in NIS and SCRI , Arumbakkam, Chennai.
- The raw drugs will be purified and the medicine will be prepared as per SOP in Gunapadam Laboratory of National Institute of Siddha.

9.1 Purification of raw drugs

The following drugs will be purified as per siddha literature ;

1. Root of Sivathai *(Operculina turpethum.Linn.*- steamed with milk and dried.
2. Root of Nilavagai *(Cassia senna,Linn* - steamed with milk and dried.
3. Koraikizhangu *(Cyperus rotandus)* - Remove the outer skin and shadow dry.
4. Sukku (*Zingiber officinalis.Rosc*)- Peel off the outer skin
5. Milagu *(Piper nigrum.Linn*)-Soak it in butter milk for three hours and dry it.
6. Thippili(*Piper longum.Linn)* -Soak it in butter milk for three hours and dry it.
7. Kadukkai *(Terminalia chebula.Retz)*-Discard the seed and collect the rinds alone for use.
8. Thaantrikkai (*Terminalia bellarica.Roxb)*- Discard the seed and collect the rinds alone for use.
9. Nellikkai *(Phylanthus embilica.Linn)*- Remove the seed and collect the rinds alone for use.
10. Kanda Thippili(*Piper longum.Linn*)-Soak it in butter milk for three hours & dry.
11. Indhuppu *(Sodium chloride impura)*-soaked in viniger for three days and dried in sunlight.
12. Omam (*Carum coptium.Benth&Hook.f*)-Soak it in clear calcium carbonate filtrate and dry it.
13. Kadugu Rogini *(Picrorhiza scrophulariflora,Pennell)*-Dry it in shade.
14. Vaaivilangam *(Embelia ribes.Burm)* -Remove the waste from it and dry it in shade.

15. Athividayam (*Aconitum heterophyllum Wall-ex Royle)*-Dry it in shade
16. Maasikai *(Quercus infectoria.Oliver*)-Dry it in shade.
17. Raipur Sugar *(Brown sugar)*-Dissolved in water and filter it.
18. Sitramanakku ennai *(Ricinus communis.Linn)*-Filter it.
19. Water-Filter it.

9.2 Preparation:

Garpa vaayu ilagam: Ref:Vaithiya saarasangiragam,P.no-59

9.3 Ingredients:

1. Sivathai vaer *(Operculina turpethum.Linn)* - 150 varagan (630 gm)
2. Nilavagai vaer *(Cassia senna,Linn)* -150 varagan (630 gm)
3. Koraikizhangu *(Cyperus rotandus,Linn)* -33 varagan (132 gm)
4. Sukku *(Zingiber officinalis.Rosc)* - 1.7 gm
5. Milaghu *(Piper nigrum.Linn)* - 1.7gm
6. Thippili *(Piper longum.Linn)* - 1.7 gm
7. Kadukai *(Terminalia chebula.Retz)* - 1.7 gm
8. Thaantrikkai *(Terminalia bellarica.Roxb)* - 1.7 gm
9. Nellikkai *(Phylanthus embilica.Linn)* - 1.7 gm
10. Kanda Thippili(*Piper longum.Linn*) - 1 kazhanju (5.1 gm)
11. Indhuppu *(Sodium chloride impura)* - 1 kazhanju (5.1 gm)
12. Omam *(Carum coptium.Benth&Hook)* - 1 kazhanju (5.1 gm)
13. Kadugu Rogini *(Picrorhiza scrophulariflora,Pennell)* - 1 kazhanju (5.1gm
14. Vaaivilangam *(Embelia ribes.Burm)* - 1 kazhanju (5.1gm)
15. Athividayam (*Aconitum heterophyllum Wall-ex Royle*- 1 kazhanju (5.1 gm)
16. Maasikai *(Quercus infectoria.Oliver*) - 1 kazhanju (5.1 gm)
17. Raipur Sugar(Brown sugar) - 5 palam (175 gm)
18. Sitramanakku ennei *(Ricinus communis,Linn)* -1 padi (1.3 litre)
19. Water - Suffiecient quantity
20.

9.4 **METHOD OF PREPERATION:** The purified raw drugs from 1 to 16 will be made into fine powder. The powder will be added to the sugar syrup (i.e 175 gms of powdered sugar required quantity of water will be added and boiled till it reaches syrup consistency) and mix it well until it reach to ilagam consistency. Then Castor oil-1.3litre will be added to the above mixture.

9.5 Drug Storage:

The prepared drug will be stored in clean and dry air tight glass container.

9.6 Dispensing:

The Ilagam will be dispensed in a glass container per visit.

10.0 Subject selection:

Patients reporting at OPD of maruthuvam with the symptoms of inclusion criteria will be subjected to screening test and documented using screening proforma.

11.0 INCLUSION CRITERIA:

- Age: 20-40 years
- Patients who are having the clinical symptoms of Oligomenorrhoea (or) Amenorrhoea (or) Dysmenorrhoea.
- Patient willing to undergo Ultrasound abdomen & routine blood investigation.
- USG pelvis showing polycystic ovaries.
- Patient willing to participate in trial and signing in consent form

12.0 EXCLUSION CRITERIA:

- H/O hypertension
- H/O Diabetes mellitus
- H/O cardiac disease
- Pregnancy and lactation
- H/O thyroid dysfunction
- Chronic kidney disease
- Fibroid uterus
- H/O use of HRT in one year before.
- Presence of any systemic illness (e.g.Anaemia,)

13.0 WITHDRAWAL CRITERIA:

- Intolerance to the drug and development of adverse reactions during the drug trial.
- Poor patient compliance & defaulters
- Patients turned unwilling to continue in the course of clinical trial
- Severe abdominal pain
- Heavy menorrhagia

14.0TEST AND ASSESSMENTS:

14.1 Clinical assessment

14.2 Siddha assessment

14.3 Routine Investigations

14.4 Specific investigation

14.1 Clinical Assessment:

- Irregular menstruation
- Amenorrhoea
- Oligomenorrhoea
- Obesity
- Hirsuitism
- Acanthosis nigricans
- Obesity
- Infertility
- Constipation

14.2 Siddha Assessment

- Naadi
- Sparisam
- Naa
- Niram
- Mozhi
- Vizhi
- Malam
- Moothiram
    - Neerkuri
    - Neikuri

14.3 Routine Tests and Investigations

Blood:

- Hb (gms/dl)
- Total RBC (million/cu.mm)
- Total WBC (cubic mm)
- Differential count :(%)

  Polymorphs

  Lymphocytes

  Monocytes

  Esinophils

  Basophils

- ESR(mm/hr)
- **Blood sugar level -** Fasting (mg/dl)

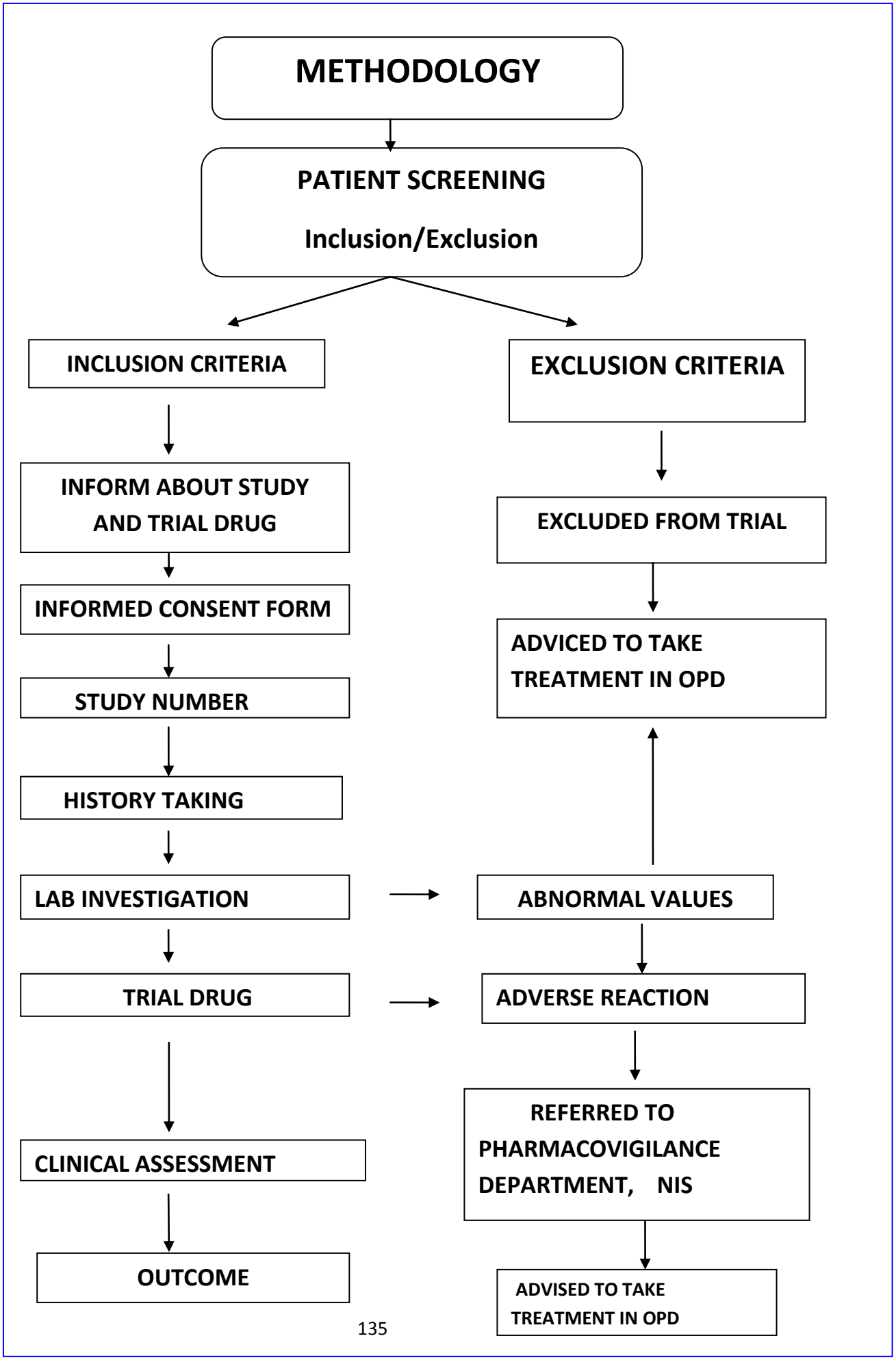
  Post prandial (mg/dl)

  Random (mg/dl)

- **Lipid profile**
- **Renal function test**
- **Liver function test**
- **Urine**
- **Thyroid function test**

14.4 Specific Investigations

Ultra Sonography:USG Pelvis


METHODOLOGY
PATIENT SCREENING
Inclusion/Exclusion
INCLUSION CRITERIA
EXCLUSION CRITERIA
INFORM ABOUT STUDY AND TRIAL DRUG
INFORMED CONSENT FORM
STUDY NUMBER
HISTORY TAKING
LAB INVESTIGATION
TRIAL DRUG
CLINICAL ASSESSMENT
OUTCOME
EXCLUDED FROM TRIAL
ADVICED TO TAKE TREATMENT IN OPD
ABNORMAL VALUES
ADVERSE REACTION
REFERRED TO PHARMACOVIGILANCE DEPARTMENT, NIS
ADVISED TO TAKE TREATMENT IN OPD

15.0STUDY ENROLMENT:

Patient reporting at the NIS, OPD with clinical features of Amenorrhoea, Oligomenorrhoea, obesity, Irregular menstruation, infertility are chosen for enrolment based on the inclusion criteria. The patients who are enrolled are informed about the study trial drug, possible outcomes and the objectives of the study in their own language and terms understandable to them and the informed consent would be obtained from them in the consent form.

16.0 **CONDUCT OF THE STUDY:**

On the first day the trial drug Garpa vaayu ilagam was given for 7 days medicine-7 days drug holiday for 3 months. The trial drug was given by the investigator in the OP department of Maruthuvam, NIS, Chennai. The patients will be asked to have a regular treatment in the OP department once in 14 days . In every visit the clinical assessment will be recorded in the prescribed Proforma (form no:II A). The laboratory investigation will be done before and after treatment and recorded in the prescribed format (form no: III).

At the end of the trial the patients will be advised to come for follow up for 2 months for observation.

17.0 Data Management:

- After enrolling the patient in the study, a separate file for each patient will be opened and all forms will be filed in the file. Study No. and Patient No. will be entered on the top of file for easy identification. Whenever the study patient visits OPD during the study period, the respective patient's file will be taken and necessary recordings will be made at the assessment form or other suitable forms.
- The screening forms will be filed separately.
- The Data recordings will be monitored for completion by Guide (HOD, Dept. of Maruthuvam), SRO (Statistics) and the adverse event will be monitored by the members of the Pharmacovigilance department of NIS. All forms will be further scrutinized in presence of Investigator by Sr.Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results is permitted for unbiased reports.

18.0STATISTYCAL ANALYSIS :

All collected data will be entered into computer using MS access / MS excel software by the investigator. The data will be analyzed using STATA software under the guidance of SRO(stat),NIS. The level of significance will be 0.05 Descriptive analysis will be made and necessary tables/graphs generated to understand the profile of the patients included in the study. Student 't' test and chisquare test are proposed to be performed for quantitative and qualitative data.

19.0OUTCOME OF TREATMENT

19.1PRIMARY OUTCOME:

It is assessed by the changes of the ovaries in USG pelvis and improvement in the score of intermenstrual period before and after treatment.

INTERMENSTRUAL PERIOD

IMP (days)	Grade	Score
28 days	Nil	0
28 - 45	Mild	1
45 - 60	Moderate	2
Above 60	Severe	3

19.2 SECONDARY OUTCOME :

To reduce the clinical symptoms such as Irregular menstruation Amenorrhoea, Oligomenorrhoea, Obesity, etc.

20.0Adverse effect and Serious effect Management:

If the trial patient develops any adverse reactions the patient will be referred to the Pharmacovigilance department of NIS and documented. For any adverse effect the investigator will give the proper management in the OPD.

21.0ETHICAL ISSUES:

1. Informed consent will be obtained from the patients after explaining about the clinical trial in an understandable language.
2. After the consent of the patient (through consent form) they will be enrolled in the study.
3. Treatment will be provided free of cost
4. No other medicines will be used except the trial drug

5. USG- Abdomen will be taken in the NABL certified laboratories and charges will be borne by the patient.
6. To prevent any infection, while collecting blood sample from the patient, only

   Disposable syringes, disposable gloves, with proper sterilization of lab equipments will be used.
7. The data collected from the patient will be kept confidentially. The patient will be informed about the diagnosis, treatment and follow up.
8. The patients who are excluded (as per the exclusion criteria) are given proper treatment with full care at OPD.
9. In conditions of treatment failure, adverse reactions patients will be given alternative treatment at the OPD with full care through the end.

22.0 DATA COLLECTION FORMS:

Required information will be collected from each patient by using the following forms

Forms:

FORM l **:** Screening & Selection Proforma

FORM ll : Clinical Assesment form

FORM lll : Laboratory Investigation form

FORM IV: Drug compliance form

FORM V : PatientInformation Sheet

FORM VI : InformedConsent Form

FORM VII: Withdrawal Form/ Adverse reaction form (Pharmacovigilence form)

FORM VIII : Dietary advice Form

CASE REPORT FORM

DISSERTATION TITLE

CLINICAL EVALUATION OF SIDDHA DRUG GARPAVAAYU ILAGAM
IN THE TREATMENT OF GARPAVAAYU
(POLYCYSTIC OVARIAN SYNDROME)

CENTRE

AYOTHID0SS PANDITHAR HOSPITAL
NATIONAL INSTITUTE OF SIDDHA
CHENNAI-47

INVESTIGATOR

DR.S.SHAGILA MD(S)
PG SCHOLAR
DEPARTMENT OF MARUTHUVAM
NATIONAL INSTITUTE OF SIDDHA
CHENNAI-47

GUIDE

DR.T.LAKSHMI KANTHAM, M.D(S)
LECTURER,
DEPARTMENT OF MARUTHUVAM
NATIONAL INSTITUTE OF SIDDHA
CHENNAI-47

Signature of the Guide Signature of the HOD

FORM l - SCREENING AND SELECTION PROFORMA

1.SERIAL NO: 2.OP/IP NO: ……

3.NAME: …….. 4.AGE: …… 5.GENDER: M / F 6.RELIGION: H/C/M/O

7. ADDRESS:

8.CONTACT NO:

INCLUSION CRITERIA

- Age:20-40 yrs Yes / No
- Patients who are having the symptoms of Oligomenorrhoea (or) Amenorrhoea (or) Dysmenorrhoea Yes / No
- Patient willing to undergo USG pelvis & routine blood investigation Yes / No
- USG pelvis shows polycystic ovaries Yes / No
- Patient willing to participate in trial and signing in consent form Yes / No

EXCLUSION CRITERIA:

- History of hypertension Yes / No
- History of diabetes mellitus Yes / No
- History of cardiac disease Yes / No
- Pregnancy and lactation Yes / No
- History of thyroid dysfunction Yes / No
- History of recent hormone therapy (Past one year) Yes / No
- Presence of any systemic illness (e.g.Anaemia,)Yes / No
- Chronic kidney disease Yes / No
- Fibroid uterus Yes / No

ADMITTED TO TRIAL

YES ☐ NO ☐

If Yes Serial NO: ☐☐

Signature of the Investigator with date:

FORM II-CLINICAL ASSESSMENT FORM

1. **Patient ID**: _____ 2. **S.NO**: _____

3. **Occupation**: _____ 4.**Income**: _____

5. **Educational Status**: A) Illiterate ☐ B) Literate ☐

6. **Date of informed consent signed**: _____

7. **Height**: _____cms 8.**Weight**: ____ kg 9.**BMI**: _____

10. **COMPLAINTS&DURATION**: _____

_____

11. **DIET:**A.Pure vegetarian ☐ B.Non-vegetarian ☐ If yes, No of times ____per month

C.Mixed diet ☐

12. **HABIT OF**

A) Smoking 1. Yes; duration _____ years; number _____ 2.No

B) Tobacco chewing 1. Yes; duration _____ years 2.No

C) Betel chewing 1. Yes; duration _____ years 2.No

D) Alcoholism 1.Yes; duration _____ years; Quantity____ml 2.No

E) Coffee or Tea 1.Yes; No of times _____ per day. 2.No

13.**DRUG HISTORY**: Had the patient been treated before with allopathy drug for anaemia or any other ailments?

A.YES ☐ B.NO ☐ IF YES : : _____

14. MARITAL STATUS: 1.Married ☐ 2.Unmarried ☐

No of children: ☐ male: ☐ female: ☐

15. FAMILY HISTORY:

Whether this problem runs in family? 1.Yes ☐ 2.No ☐

If yes, mention the relationship of affected person(s) ----------

16. MENSTURAL AND OBSTETRIC HISTORY:

1. Age at menarche _____ year

2. Regularly of cycle Regular ☐ Irregular ☐

3. Length of cycle [Days]

4. Duration of flow [Days]

5. Level of flow Low ☐ Moderate ☐ Heavy ☐

6.LMP :

7. Passage of big clots Yes / No

8. Dysmenorrhoea started at age _____ years

9. Onset of abdominal pain

Starts at the time of menstruation Prior by _____ hours ☐

At that time ☐

After _____ hours ☐

10. Presence of abdominal pain other than around the time of menstruation

1. Yes ☐ 2.No ☐

11. Presence of hirsuitism 1.Yes ☐ 2.No ☐

12. Drug history: H/O Previous hormonal therapy 1. Yes ☐ 2.No ☐

17. BOWEL HABITS & MICTURITION: Normal

Historyof habitual constipation 1.Yes ☐ 2.No ☐

History of frequent diarrhoea 1.Yes ☐ 2.No ☐

History of frequent dysuria 1.Yes ☐ 2.No ☐

☐ ☐

18. **PSYCHOLOGICAL STATE:** Normal A☐ety Depression

19. **THEGI: [TYPE OF BODY CONSTITUTION]**

1.Vatham ☐ 2.Pitham ☐ 3.Kabam ☐ IF NO 4. _____

20. NILAM: [LAND WHERE PATIENT LIVED MOST]

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Paalai ☐

21. KAALAM: [SEASON]

Kaarkalam ☐ Koothirkalam ☐ Munpanikalam ☐

Pinpanikalam ☐ Ilavenil ☐ Muthuvenil ☐

22. GUNAM:[CHARACTER]

Sathuvam ☐ Rasatham ☐ Thamasam ☐

23.SIDDHA SYSTEM OF EXAMINATION:

ENVAGAI THERVU:[EIGHT-FOLD EXAMINATION]

I.NAADI: [PULSE PERCEPTION]

	BEFORE TMT	**AFTER TMT**
Vali		
Azhal		
Iyyam		
Vali Azhal		
Azhal vali		
Iyya vali		
Vali Iyyam		
Azhal Iyyam		
Iyya Azhal		

II.NAA: [TONGUE]

	BEFORE TMT	**AFTER TMT**
Colour	normal/Red pale/yellow	normal/Red pale/yellow
Taste	Sweet/Sour/ Pungent/Bitter/ None	Sweet/Sour/ Pungent/Bitter /None
Coating	Present/Absent	Present/Absent
Fissure	Present/Absent	Present/Absent
Saliva	Normal/Increased/ Decreased	Normal/Increased/ Decreased
Dryness	Present/Absent	Present/Absent
Glossitis	Present/Absent	Present/Absent
Baldness	Present/Absent	Present/Absent

III.NIRAM:[COMPLEXION]

BEFORE TMT	**AFTER TMT**
Dark/pale/Yellow tinted/wheatish brown	Dark/pale/ Yellow tinted/ wheatish brown

IV.MOZHI:[VOICE]

BEFORE TMT	**AFTER TMT**
Medium/High/ Low pitched	Medium/High/ Low pitched

V.VIZHI:[EYES] (Lower palpebral conjunctiva)

BEFORE TMT	**AFTER TMT**
normal/Red pale/yellow	normal/Red pale/yellow

VI. MALAM:[BOWEL HABITS / STOOLS]

	BEFORE TMT	**AFTER TMT**
Colour	Dark/pale/yellow/Red	Dark/pale/yellow/Red
Consistency	Solid/Semisolid/Watery	Solid/Semisolid/Watery
stool bulk	Normal/Reduced	Normal/Reduced
Constipation	Present/Absent	Present/Absent
Diaarhoea	Present/Absent	Present/Absent

VII.MOOTHIRAM:[URINE EXAMINATION]

Neerkkuri	**BEFORE TMT**	**AFTER TMT**	**Neikkuri**	**BEFORE TMT**	**AFTER TMT**
Niram[Colour]	Yellow/Red/White/ Straw coloured/ Crystal clear	Yellow/Red/White /Straw coloured/ Crystal clear	Serpentine fashion		
Manam[Odour]	Present/Absent	Present/ Absent	Annular/Ringed fashion		
Nurai[Froth]	Nil/Reduced/Increasd	Nil/Reduced/Increased	Pearl beaded fashion		
Edai[Sp.gravity]	Normal/Increasd/Reduced	Normal/Increased/ Reduced	Mixed fashion		
Enjal[Deposits]	Present/ Absent	Present/ Absent	Other fashion		
Volume	Normal/Increasd/ Reduced	Normal/Increased/ Reduced			

VIII. SPARISAM:[PALPATORY PERCEPTION]

BEFORE TMT	**AFTER TMT**
Warmth/Hot/ cold/ Sweat	Warmth/Hot /cold/ Sweat

24.IYMPORIGAL:[SENSORY ORGANS]

	BEFORE TMT	**AFTER TMT**
	Normal/ Affected	Normal/ Affected
Mei [Skin]		
Vaai [Buccalcavity]		
Kan [Eyes]		
Mooku[Nose]		
Sevi [ear]		

25.IYMPULANGAL:[MOTOR ORGANS]

	BEFORE TMT	**AFTER TMT**
	Normal/ Affected	Normal/ Affected
Kai [upperlimb]		
Kal [lowerlimb]		
Vai[Buccal cavity]		
Eruvai[excretory organ]		
Karuvai [Reproductive organ]		

26.KOSAM:[SHEATHS]

	BEFORE TMT	**AFTER TMT**
	Normal/ Affected	Normal/ Affected
Annamaya kosam		
Pranamaya Kosam		
Manonmayakosam		
Vingyanamaya kosam		
Anandhamaya kosam		

27. MUKKUTRAM:[AFFECTION OF THREE HUMORS]

A)VATHAM:

	BEFORE TMT	**AFTER TMT**
	Normal/ Affected	Normal/ Affected
Praanan		
Abaanan		
Samaanan		
Udhaanan		
Viyaanan		
Naahan		
Koorman		
Kirukaran		
Devathathan		
Dhananjeyan		

B) PITHAM:

	BEFORE TMT	**AFTER TMT**
	Normal/ Affected	Normal/ Affected
Analapitham		
Prasakam		
Ranjakam		
Aalosakam		
Saathakam		

C) KABAM:

	BEFORE TMT	**AFTER TMT**
	Normal/ Affected	Normal/Affected
Avalambagam		
Kilethagam		
Pothagam		
Tharpagam		
Santhigam		

28.SEVEN DHATHUS:[SEVEN SOMATIC COMPONENTS]

	BEFORE TMT	**AFTER TMT**
	Normal/ Affected	Normal/ Affected
Saaram[chyme]		
Senneer[Blood]		
Oon[Muscle]		
Kozhuppu[Fat]		
Enbu[Bones]		
Moolai[Bonemarrow]		
Sukkilam/Suronitham [Genital discharges]		

29.GENERAL EXAMINATION:

	BEFORE TMT	**AFTER TMT**
Height (cms)		
Weight (kg)		
Temperature(°F)		
Pulse rate (per min)		
Heart rate (per min)		
Respiratory rate(per min)		
Blood pressure(mm/Hg)		
Pallor		
Jaundice		
Cyanosis		
Lymphadenopathy		
Pedal edema		
Clubbing		
Jugular vein pulsation		

30.SYSTEMIC EXAMINATION:

	BEFORE TMT	**AFTER TMT**
CardioVascular system		
Respiratory System		
Gastrointestinal system		
CentralNervous system		
Endocrine System		

CLINICAL SYMPTOMS:

	0th day	**14th day**	**28th day**	**42nd day**	**56th day**	**70th day**	**84 th day**
Irregular menstruation							
Oligomenorrhoea							
Amenorrhoea							
Dysmenorrhoea							
Constipation							
Weight gain							
Infertility							
Acanthosis nigricans							
Hirsuitism							

Signature of the Investigator with date:

FORM III LABORATORY INVESTIGATION FORM

1. Serial No: _____ 2 .Patient ID:_____ 3.Date:_____

BLOOD INVESTIGATION		Before treatment Date:	After treatment Date:	NORMAL VALUES
HB (gms %)				11-15
T.RBC(milli/cu.mm)				3.5-5.5
ESR (mm)	½ hr.			
	1 hr.			0-20
T.WBC (cu.mm)				4000-11,000
DIFFERENTIAL COUNT (%)	Polymorphs			40-75
	Lymphocytes			20-35
	Monocytes			2-10
	Eosinophils			1-6
	Basophils			0-1
Blood glucose (mg/dl)	Fasting			80-120
	PP			<130
	Random			<140
Lipid profile (mg/dl)	Serum cholesterol			150-250
	HDL			30-60
	LDL			Upto 130
	VLDL			40
	TGL			Upto 160
RFT (mg/dl)	Blood urea			16-50
	Serum creatinine			0.6-1.2
	Serum Uric acid			2.5-7.5
LFT (mg/dl)	Total bilirubin			0.2-1.2
	Direct bilirubin			0.1-1.2
	Indirect bilirubin			0.2-0.7
	Serum total protein			6-8
	Serum Albumin			3.5-5.5
	Serum globulin			2-3.5
	Serum fibrinogen			
	Serum calcium			9-11
	Serum phosphorous			2-5
	SGOT IU/L			0-40
	SGPT IU/L			0-35
	Alkaline phosphatase IU/L			80-290

URINE INVESTIGATION	Before TMT Date:	After TMT Date:
Albumin		
Fasting sugar		
PP sugar		
Random Sugar		
Deposits		
Bile salts		
Bile pigments		
Urobilinogen		

USG PELVIS	Before treatment Date:	After treatment Date:

Signature of the Investigator with date:

FORM IV (DRUG COMPLIANCE FORM)

PATIENT ID : ---------- SERIAL NO :---------- DRUG NAME:GARPAVAYU ILAGAM

On0th day-Date: _____; Drugsissued:42gm Drugs returned:____gm

On14th day-Date:_____; Drugsissued:42gm Drugs returned:____gm

On28th day-Date:_____; Drugsissued:42gm Drugs returned:____gm

On42rd day-Date:_____; Drugsissued:42gm Drugs returned:____gm

On56th day-Date:_____; Drugsissued:42gm Drugs returned:____gm

On70th day-Date:_____; Drugsissued:42gm Drugs returned:____gm

Day	Date	Morning	Day	Date	Morning
Day1			Day43		
Day2			Day44		
Day3			Day45		
Day4			Day46		
Day5			Day47		
Day6			Day48		
Day7			Day49		
Day8 to Day14-Drug holiday			Day50 to Day 56-Drug holiday		
Day15			Day57		
Day16			Day58		
Day17			Day59		
Day18			Day60		
Day19			Day61		
Day20			Day62		
Day21			Day63		
Day22 to Day28-Drug holiday			Day64 to Day70-Drug holiday		
Day29			Day71		
Day30			Day72		
Day31			Day73		
Day32			Day74		
Day33			Day75		
Day34			Day76		
Day35			Day77		
Day36 to Day 42-Drug holiday			Day78 to Day84-Drug holiday		

FORM V- PATIENT INFORMATION SHEET

Name of the Principal Investigator: Dr.S.SHAGILA (PG Scholar)

Name of the Institution : National Institute of Siddha, Chennai-47.

IDr.S.Shagila studyingM.D (Siddha) in National Institute of Siddha, Chennai. I am doing a clinical trial on the study of Garpa vaayu(Polycystic ovarian syndrome).It is the most common gynaecological endocrinopathy with ovarian expression of metabolic disturbances. Nowadays the incidence of PCOD is much higher because of changes in life style like dietary habits, lack of physical work, stressful work.It includes symptoms of irregular menstruation like absence of mensturation, painful mensturation, and increased body weight .This condition is being treated in NIS with many siddha formulations. As a part of M.D(S) research programme and developing new efficacious medicine, I have proposed to study the drug Garpavayu ilagam for treating this condition. This formulation has been mentioned in siddha literature and empirical evidence with contemporary tools is required for documentation. You can receive medicines free of cost. The duration of treatment period is 3months. You have to visit NIS 15 days once and collect drugs for 7 days. The diagnosis tests will be carried out free of cost. However, a particular test USG Abdomen has to be taken from outside lab and charges to be borne by you. We will assess the effect of treatment after completion of 3months of treatment using clinical and lab parameters.

In this regard, I need to ask you few questions. I will maintain confidentiality of your comments and data obtained from you. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study.

Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study. You can choose not to answer any specific question. There is no specific benefit for you if you take part in the study, but you will be under our clinical monitoring and specific attention will be given for your health. Taking part in the study may be of benefit to the community, as it may help us to develop medicine for Garpa vaayu. In case of any adverse symptoms like severe abdominal pain, menorrhagia during the treatment shall be reported to me and care will be taken in NIS for relief. You can withdraw from the study at the midst of treatment period, if you are not interested to continue and you will receive our usual treatment without condition.

The information collect in this study, will remain between you and me as a principal investigator. I will ask you a few questions through questionnaire. I will not write your name on different forms which sent to different investigating/analysis sections and I will use a code instead given by the principal investigator. Only the principal investigator will know the key to this code which will be kept in safe custody. If you agree to be a participant in this study, you will be screened as per the study protocol.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contactDr.S.Shagila, PG scholarprincipal investigator of this study, attached to the National Institute of Siddha, Chennai (Mobile phone no:9787646890). You can also contact the Chairman/Member-secretary of Ethics committee, National Institute of Siddha, Chennai – 600047, Tel no: 91-44-22411611, for rights and participation in the study.

FORM V- தகவல் படிவம்

முதன்மை ஆராய்ச்சியாளர் பெயர் : Dr. சு.ஷகிலா
நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்
தாம்பரம் சானட்டோரியம்
சென்னை 47

Dr.சு.ஷகிலா ஆகிய நான் தேசிய சித்த மருத்துவமனையில் பட்ட மேற்படிப்பு பயின்று வருகிறேன். **கெர்ப்ப வாயு** என்னும் நோயானது சினைப்பையில் நீர்கட்டிகளை ஏற்படுத்தும் ஒரு நோயாகும். இந்நோயானது ஒழுங்கற்ற மாதவிடாய்,சூதகதடை,சூதகவலி,உடல்பருத்தல்,கர்ப்பத்தினை அழித்தல்,முகத்தில் தோன்றும் தேவையற்ற முடி வளர்ச்சி,மலச்சிக்கல் போன்ற குறிகுணங்களைத் தோற்றுவிக்கும். இந்நோய்க்கு தேசிய சித்த மருத்துவமனையில் பல சித்த மருந்துகள் பயன்படுத்தப்பட்டு வருகின்றது. சித்த மருத்துவ பட்ட மேற்படிப்பில், ஆய்வின் ஒரு பகுதியாக புதிய மருந்துகளை பயன்படுத்தும் நோக்கில் **கெர்ப்பவாயு இளகம்** என்னும் மருந்தினை இந்நோய்க்கு வழங்க பரிந்துரை செய்கிறோம். இந்த மருந்தின் செய்முறை, அளவு, அனுபானம் மற்றும் மருத்துவ பயன்கள் அனைத்தும் அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது. எந்தவித கட்டணமுமின்றி தாங்கள் இந்த மருந்தினை பெற்றுக்கொள்ளலாம். இந்த ஆய்வில் மருந்து உட்கொள்ளும் காலம் **3 மாதங்கள்** ஆகும். 14 நாள்களுக்கு ஒருமுறை தேசிய சித்த மருத்துவமனைக்கு நேரில் வந்து மருந்தினை பெற்றுக்கொள்ள வேண்டும். இந்த ஆய்வு சம்பந்தமான ஆய்வக பரிசோதனைகள் கட்டணமின்றி செய்யப்படும். மேலும் இந்நோய்க்கான, குறிப்பிட்ட **USG ABDOMEN** பரிசோதனை வெளி ஆய்வுக்கூடத்தில் தங்கள் செலவிலேயே செய்து கொள்ள வேண்டும். 3 மாதங்கள் மருந்து உட்கொள்ளும் காலம் முடிந்த பிறகு நோய்க்கான குறிகுணங்கள் மற்றும் ஆய்வக பரிசோதனைகள் இவற்றின் முடிவுகளின் அடிப்படையில் மருந்தின் பரிகரிப்புத்திறன் கண்டறியப்படும்.

இந்த ஆய்வு சம்பந்தமாக சில கேள்விகளை தங்களிடம் கேட்க இருக்கிறேன். தங்களிடமிருந்து பெறப்படும் கருத்துக்கள் மற்றும் குறிப்புகள் அனைத்தும் நம்பிக்கையாக பதிவு செய்யப்படும்.இந்த ஆய்வில் தங்களை உட்படுத்திக்கொள்வதின் மூலம் எந்த வகையிலும் பாதிப்புக்குள்ளாக மாட்டீர்கள் என உறுதி அளிக்கிறேன்.

எந்தவித வற்புறுத்தலுமின்றி, இந்த ஆய்வில் பங்கேற்கவும், இந்த ஆய்வு சம்பந்தமாக கேட்கப்படும் கேள்விகளுக்கு பதில் கூறவும் தங்களுக்கு முழு சுதந்திரம் அளிக்கப்படுகிறது. இந்த ஆய்வில் பங்கேற்பதற்கு எந்த சன்மானமும் வழங்கப்படமாட்டாது. ஆனால், ஆய்வு முழுவதும் எனது மேற்பார்வையிலும், தங்கள் உடல்நலன் குறித்த தனி கவனத்திலும் ஆய்வு மேற்கொள்ளப்படும். கெர்ப்ப வாயு நோய்க்கான புதிய மருந்தின் பரிகரிப்புத்திறனை சமூகத்திற்கு உணர்த்தும் வகையில் இந்த ஆய்வு மேற்கொள்ளப்படுகிறது. இந்த ஆய்வில், மருந்து உட்கொள்ளும் காலத்தில் சிலருக்கு பெரும்பாடு, தாங்கமுடியாத வயிற்று வலி போன்ற மாறுபட்ட குறிகுணங்கள் தொடர்ந்து இருக்கும் பட்சத்தில், முதன்மை ஆராய்ச்சியாளரான என்னிடம் தெரிவிக்கப்பட்டு, தேசிய சித்த மருத்துவமனையில் அதற்க்கான தீர்வு வழங்கப்படும். இந்த ஆய்வினைத் தொடர தங்களுக்கு விருப்பம் இல்லையெனில், எப்பொழுது வேண்டுமானலும் ஆய்வின் இடையில் விலகிக்கொள்ளவும், இம்மருத்துவமனையில் வழங்கப்படும் இந்நோய்க்கான வழக்கமான மருந்துகளை பெற்றுக்கொள்ளவும் அறிவுறுத்தப்படுகிறீர்கள்.

இந்த ஆய்வில் சேகரிக்கப்படும் விபரங்கள் அனைத்தும் தங்களுக்கும் முதன்மை ஆராய்ச்சியாளரான எனக்கும் இடையில் இரகசியமாக வைக்கப்படும். கேள்வி பதில் வடிவத்தில் தங்களிடம் கேள்விகள் கேட்கப்படும். அனைத்துப் படிவங்களிலும் தங்களின் பெயர் தவிர்க்கப்பட்டு ஆய்வாளரால் தங்களுக்கென தனிக் குறியீடு வழங்கப்படும். அந்தக் குறியீடு ஆய்வாளருக்கு மட்டுமே தெரிந்ததாக இருக்கும். நீங்கள் இந்த ஆய்வில் பங்கேற்க விருப்பப்பட்டால், திட்ட வரைவு படி தேர்வு செய்யப்படுவீர்கள்.

நீங்கள் இந்த ஆய்வில் பங்கேற்கும் முன், இந்த ஆய்வினைப் பற்றிய மேலும் விபரங்கள் பெற வேண்டுமென விருப்பப்பட்டால், இந்த ஆய்வின் முதன்மை ஆராய்ச்சியாளர் மற்றும் தேசிய சித்த மருத்துவமனை, பட்ட மேற்படிப்புத்துறை மாணவர் Dr.சு.ஷகிலா ஆகிய என்னை 9787646890 என்ற எண்ணில் தொடர்பு கொள்ளலாம். மேலும், நீங்கள் இந்த ஆய்வில், உங்களது பங்கேற்பு மற்றும் உரிமை பற்றி தெரிந்து கொள்ள தேசிய சித்த மருத்துவமனை, தலைவர்/செயற்க்குழு உறுப்பினர் அவர்களையும் 91-44-22411611 என்ற எண்ணில் தொடர்பு கொள்ளலாம்.

FORM VI –INFORMED CONSENT FORM

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant: Signature of the investigator:

IN CASE OF ILLITERATE PARTICIPANT

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely."

Date:

Signature of a witness : Left thumb Impression of the Participant:

Signature of the Investigator & Date:

FORM VI-ஒப்புதல் படிவம்

நான் மேற்கூறிய தகவல் படிவத்தை படித்து அல்லது படிக்க கேட்டு கொண்டேன். இது தொடர்பான விளக்கங்களையும் கேட்டு தெரிந்து கொண்டேன்.எந்த வித வற்புறுத்தலின்றி, என் சொந்த விருப்பத்தின் பேரில் என்னை இந்த ஆராய்ச்சிக்கு உட்படுத்த என் முழுமனதோடும் சுயநினைவோடும் சம்மதம் தெரிவிக்கிறேன்.எனக்கு விருப்பமில்லாத பட்சத்தில் இந்த ஆராய்ச்சியில் இருந்து என்னை எப்போதுவேண்டுமானாலும் விடுவித்து கொள்ளும் உரிமையை பெற்றுள்ளேன் என்பதையும் அறிவேன்.

தேதி:

இடம்: சாட்சிக்காரர் கையொப்பம்:

பெயர்:

கையொப்பம்: உறவுமுறை :

பெயர் :

FORM VII- (WITHDRAWAL FORM/ADVERSE DRUG REACTION FORM/

PHARMACOVIGILANCE FORM)

1. DATE OF TRIAL COMMENCEMENT: ……...

2. DATE OF WITHDRAWAL FROM TRIAL: ……..

3. REASONS FOR WITHDRAWAL:

Long absence at reporting:	Yes/ No
Irregular treatment:	Yes/ No
Shift of locality:	Yes/No
Increase in severity of symptoms:	Yes/No
Development of severe adverse drug reactions:	Yes/No

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS

Please note: i. All consumers / patients and reporters information will remain confidential.

ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

Peripheral Center code: State:

1. **Patient / consumer identification (please complete or tick boxes below as appropriate)**

Name	Father name	Patient / Record No.
Ethnicity	Occupation	
Address Village / Town Post / Via District / State		Date of Birth / Age: Sex: Male / Female Weight : Degam:

2. Description of the suspected Adverse Reactions (please complete boxes below)

Date and time of initial observation		Season:
Description of reaction		Geographical area:

3. List of all medicines / Formulations including drugs of other systems used by the patient during the reporting period:

Medicine	Daily dose	Route of administration & Vehicle – Adjuvant	Date		Diagnosis for which medicine taken
			Starting	Stopped	
Siddha					

Anyother systemofmedicines					

4. Brief details of the Siddha Medicine which seems to be toxic:

Details	Drug – 1	Drug – 2	Drug – 3
a) Name of the medicine			
b) Manufacturing unit and batch No. and date			
c) Expiry date			
d) Purchased and obtained from			
e) Composition of the formulation / Part of the drug used			

b) Dietary Restrictions if any

c) Whether the drug is consumed under Institutionally qualified medical supervision or used as self medication.

d) Any other relevant information.

5. Treatment provided for adverse reaction:

6. The result of the adverse reaction / side effect / untoward effects (please complete the boxes below)

Recovered:	Not recovered:	Unknown:	Fatal:	If Fatal Date of death:
Severe: Yes / No.	Reaction abated after drug stopped or dose reduced:			
	Reaction reappeared after re introduction:			
Was the patient admitted to hospital? If yes, give name and address of hospital				

7. Any laboratory investigations done to evaluate other possibilities? If Yes specify:

8. Whether the patient is suffering with any chronic disorders?

Hepatic Renal Cardiac Diabetes Malnutrition

Any Others

9. H/O previous allergies / Drug reactions:

10. Other illness (please describe):

11. Identification of the reporter:

Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / Manufacturer / Distributor / Supplier / Any others (please specify)
Name:
Address:
Telephone / E – mail if any :

Signature of the reporter: **Date:**

Please send the completed form to:

Name & address of the RRC-ASU / PPC-ASU

The Director
National Institute of Siddha,
(Pharmacovigilance Regional Centre For Siddha Medicine),
Tambaram Sanatorium, Chennai-600 047.
(O) 044-22381314 Fax : 044 – 22381314
Website :www.nischennai.org
Email: nischennaisiddha@yahoo.co.in

* * * *

FORM VIII- DIETARY ADVICE FORM

The following diet to be taken:

- Drink adequate water
- Goose berry
- Green vegetables
- Fish
- Sprouted black gram
- Butter milk
- Fig fruit
- Honey
- Tender brinjal
- Bananna
- Pome granate
- Dates

The following food should be avoided: Karapan inducing foods :

- Solam(Maize),
- Kambu(Pear milet),
- Varagu (Kodo millet),
- Kaar Arici(rice) ,
- Vaazaikai(Unriped banana),
- Paagal(Bitter gourad),
- kelitrumeen(fish).

Signature of the Investigator &Date:

FORM VIII – DIETARY ADVICE FORM

சேர்க்க கூடிய உணவு வகைகள்

- நெல்லிக்காய்
- பச்சை காய்கறிகள்
- மோர்
- அத்திப்பழம்
- பேரீச்சை
- கத்திரி பிஞ்சு
- மாதுளை
- பப்பாளி
- அன்னாசிப்பழம்
- கொட்டையுள்ள கருப்பு திராட்சை
- பாசிப்பயிர்
- சோயா பீன்சு

தவிர்க்க கூடிய உணவு வகைகள்:கரப்பான் பதார்த்தங்கள்

- சோளம்
- கம்பு
- வரகரிசி
- காரரிசி
- வாழைக்காய்
- பாகல்
- கெளிற்றுமீன்

Signature of the Investigator &Date:

VENSIVATHAI

NILAVAGAI

KORAIKIZANGU

CHUKKU

MILAGU

THIPPILI

KADUKKAI

NELLIKKAI

THANDRIKKAI

]

KANDATHIPPILI

OMAM

KUROSANI OMAM

VAIVILANGAM

ATHIVIDAYAM

MAASIKKAI

KADUGUROGINI

INDHUPPU

BROWN SUGAR

SITRAMANAKKU ENNEI

GARPA VAAYU ILAGAM

Dosage : 6 gm, morning, before food

Duration : like wise 7days medicine – 7days drug holiday

Study Period : 3 months /patient

Total duration of drug administration : 42 days

NATIONAL INSTITUTE OF SIDDHA
राष्ट्रीय सिद्ध संस्थान

Department of AYUSH- MINISTRY OF HEALTH & FAMILY WELFARE
आयुष विभाग - स्वास्थ एवं परिवार कल्याण मंत्रालय
GOVERNMENT OF INDIA-भारत सरकार

TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम सनटोरियम चेन्नई -600 047

फ़ोन\Tele : 044-22411611 फैक्स\Fax : 22381314

ईमेल: nischennaisiddha@yahoo.co.in वेब :www.nischennai.org

F.No.NIS/6-20/IEC/14-15 Dt: 25.09.14

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr.S.Shagila, P.G. Student, Maruthuvam	
Protocol title: Clinical evaluation of siddha drug Garpa vaayu Ilagam in the treatment of Garpa vayu (Poly cystic ovarian syndrome)	
Documents filed	1) Protocol, 2) Data Collection forms 3) Patient Information Sheet 4) Consent form 5) SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	**Yes**
Informed consent documents	**Yes**
Any other documents	-
Date of IEC approval & its number	**NIS/IEC/8-14/6- 26-08-2014**

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent.

Chairman **Member Secretary**

NATIONAL INSTITUTE OF SIDDHA CHENNAI 600 047

ANNA NAGAR LIONS DIAGNOSTIC CENTRE
CLINICAL LAB I ECG I X-RAY I ULTRASOUND
Door No. 52/2, Patel Road, Perambur, Chennai - 600 011. Ph : 42614313, 42606214
Email : aldcperambur@gmail.com
Timings : 7 a.m. to 7 p.m. SUNDAY HOLIDAY
A Project of LIONS CLUB OF ANNA NAGAR CHARITABLE TRUST
ALDC
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Patient name	Miss. MANGAYARKARASI.J	**Age/Sex**	22 Years / Female
Patient ID	013682	**Visit No**	1
Referred by	Dr. SELF	**Visit Date**	19/11/2015

Whole Abdomen Scan Report

Real time B-mode Ultrasonography of Abdomen,KUB and Pelvis done

Abdomen

Liver filled with homogeneous parenchymal echoes. No abscess or mass lesion in the liver
liver measured 11.9cms
Gall bladder appeared normal. No calculi seen in the gall bladder
Commonduct appeared normal. No calculi seen in the commonduct.
Pancreas appeared normal
Spleen measured 8.5 X 3.1 cms.
Spleen appeared normal
Aorta appeared normal. No para aortic nodes seen.
Peritoneal cavity appeared normal
Adrenals appeared normal

KUB

Right kidney measured 9.0 X 3.5 cms.
Cortex and collecting system of right kidney appeared normal. No calculi seen.

Left kidney measured 9.6 X 4.1 cms.
Cortex and collecting system of left kidney appeared normal. No calculi seen.

Bladder appeared normal

Pelvis

Uterus measured 8.9 X 2.9 X 4.3 cms.
Normal appearing uterus with homogeneous myometrial echoes
Endometrial cavity appeared normal
Endometrial thickness measured 4.3 mm
Both ovaries are upper limits of normal in size
Multiple small peripheral cysts seen in both the ovaries
RT. Ovary measured : 3.9 X 2.0 cms. Volume : 8.1cc
LT. Ovary measured : 4.3 X 1.5 cms. Volume : 5.2cc
Both adnexae appeared normal

Impression

BILATERAL POLYCYSTIC OVARIES -- UNDER TREATMENT
--Please correlate clinically

REST OF THE STUDY SHOW NO ABNORMALITY

DR. VISHNU SRINIVAS DMRD.,
RADIOLOGIST

"Results to be correlated with patient's age, clinical symptoms, timing of food and drug intake"
Report collecting Time : 5.45 to 6.45 p.m. - Feed back and requests regarding calues will be addressed within 48 hours.

ANNA NAGAR LIONS DIAGNOSTIC CENTRE

CLINICAL LAB I ECG I X-RAY I ULTRASOUND

Door No. 52/2, Patel Road, Perambur, Chennai - 600 011. Ph : 42614313, 42606214
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Patient name	Mrs. MANGAIYARKARASI.J	**Age/Sex**	22 Years / Female
Patient ID	018934	**Visit No**	1
Referred by	Dr. SELF	**Visit Date**	13/02/2016

Whole Abdomen Scan Report

Real time B-mode Ultrasonography of Abdomen,KUB and Pelvis done

Abdomen

Liver filled with homogeneous parenchymal echoes. No abscess or mass lesion in the liver

Gall bladder appeared normal. No calculi seen in the gall bladder

Commonduct appeared normal. No calculi seen in the commonduct.

Pancreas appeared normal

Spleen appeared normal

Aorta appeared normal. No para aortic nodes seen.

Peritoneal cavity appeared normal

Adrenals appeared normal

KUB

Right kidney measured 8.8 X 2.6 cms.

Cortex and collecting system of right kidney appeared normal. No calculi seen.

Left kidney measured 8.6 X 3.6 cms.

Cortex and collecting system of left kidney appeared normal. No calculi seen.

Bladder appeared normal

Pelvis

Uterus measured 7.2 X 3.2 X 3.6 cms.

Normal appearing uterus with homogeneous myometrial echoes

Endometrial thickness measured 8.9 mm

Endometrial cavity appeared normal

Right ovary measured 2.7 X 3.2 cms.

Right ovary appeared normal.

Left ovary measured 3.1 X 2.7 cms.

Left ovary appeared normal

Minimal fluid noted in the POD

Impression

MINIMAL FLUID NOTED IN THE POD - ? P.I.D.

Normal appearing Liver, Gall Bladder, Common Duct, Pancreas, Spleen, Aorta, Peritoneal Cavity, Adrenals, Pleural Spaces, Both Kidneys, Both Ureters, Bladder, Uterus, Endometrial Cavity, Both Ovaries

SONOLOGIST

"Results to be correlated with patient's age, clinical symptoms, timing of food and drug intake"
Report collecting Time : 5.45 to 6.45 p.m. - Feed back and requests regarding calues will be addressed within 48 hours.

LOW COST HIGH QUALITY DIAGNOSTIC CARE AT ALDC

i-Scans

Lab and Diagnostic Centre

Patient Id	01593	Study Date	10-Jul-15
Name	**MRS.MAHESWARI**	Description	Pelvis
Age/ Sex	28 years/ F	Ref. Doctor	---

Real time B-mode transabdominal ultrasonography of Pelvis done.

USG - Pelvis

Uterus appears normal in size and measures:**73 X 83 X 47 mm.**

Myometrium appears normal.

Endometrial cavity appears normal. Thickness: **8 mm.**

Right Ovary measures: **32 X 27 X 17 mm.(Volume = 8 cc.)**

Left Ovary measures: **29 X 24 X 27 mm.(Volume = 10 cc.)**

Both ovaries shows multiple small follicles located at the periphery and increased stromal echogenicity.

Both adnexae appear normal.

Impression:

BILATERAL POLYCYSTIC OVARIES.

Suggested clinical/Hormonal correlations.

Dr. Noor Iqubal B.

(Consultant Radiologist)

124, Gandhi Road,
W. Tambaram, Chennai-45.
For Appointments
Call : 9677163600
appointments@i-scans.in

Samhita Scans

Sonologist : **Dr. S.B. CHITRA,** M.B.,B.S,
119, SHANMUGAM ROAD, WEST TAMBARAM, CHENNAI - 600 045.
Phone : 2226 3573 / 2226 3752

ULTRASONOGRAPHY REPORT

Name : Mrs. Maheswari Age : 28 yrs

Referred by : Dr. Shakila. Date : 7 / 4 / 2016

Real Time B mode grey scale ultrasonogram of the abdomen done.
Liver appeared normal in size with homogenous parenchymal echoes.
Hepatobiliary radicals were normal
No mass or abscess seen in the liver.
GB appeared normal,
It had smooth regular wall.
CBD was normal

Spleen appeared normal
Pancreas appeared normal

Both Kidneys appeared normal
Right Kidney measured 8.8 x 3.4 cm

Left Kidney measured 8.8 x 4 cm

Cortico medullary systems were normal
Collecting system were normal

Bladder appeared normal

~~Prostate appeared normal~~

Uterus appeared normal 4.2 x 3.2 cm
Right ovary measured 3.1 x 2.2 cms
Left ovary measured 3.3 x 2.3 cm c follicle of 1.6 cms

Paraaortic region normal

IMPRESSION Normal Abdomen Study

KR HOSPITALS
NURTURING LIVES
45 A, Mosque Street, Thirukalukundram, Kanchipuram District, T.N. 603109 Tel: 044 - 27447347/73. Mob: 9043873420.

R.No :PNA /5152 /11

A03904 29-Dec-15	A.M.Indira MBBS,MS(OG)
MS.DEEPA PERUMAL	20 F

Real time B-mode ultrasonography of Abdomen, KUB, Uterus and Ovaries done.

Abdomen

Liver filled with homogeneous parenchymal echoes. No abscess or mass lesion in the liver.
Gallbladder walls appeared normal. No calculi seen in the gallbladder.
Common duct appeared normal. No calculi seen in the common duct.
Pancreas appeared normal.
Spleen appeared normal.
Aorta appeared normal.
No free fluid in the peritoneal cavity.
No para aortic lymphadenopathy.
Adrenal glands appeared normal.

KUB

Cortex and collecting system of both kidneys appeared normal. No calculi seen.
Right Kidney measured 93 X 39 mm.
Left Kidney measured 106 X 46 mm.
Both ureters appeared normal. No dilatation seen.
Bladder appeared normal.

Pelvis

Normal appearing uterus with homogenous myometrial echoes.
Uterus measured 71 X 32 mm.
Endometrium measuring 7 mm.
Cavity echo appeared normal.
Right Ovary measured 38 X 22 mm.
Left Ovary measured 36 X 22 mm.
Both adnexae appeared normal.
Multiple small peripheral follicles seen in both ovaries
Both ovaries enlarged with echogenic stroma.

Impression

PCOD.

Dr. ELAVARASAN, DMRD.,

KR HOSPITALS
NURTURING LIVES
45 A, Mosque Street, Thirukalukundram, Kanchipuram District, T.N. 603109 Tel: 044 - 27447347/73. Mob: 9043873420.
E-mail: mc_arumugam@ymail.com

R.No :PNA /5152 /11 VALID UPTO :11/10/2016

A06252 21-May-16	A.M.Indira MBBS,MS(OG)
MRS.DEEPA PERUMAL	21 years F

Real time B-mode ultrasonography of Abdomen, KUB, Uterus and Ovaries done.

Abdomen

Liver filled with homogeneous parenchymal echoes. No abscess or mass lesion in the liver.
Gallbladder walls appeared normal. No calculi seen in the gallbladder.
Common duct appeared normal. No calculi seen in the common duct.
Pancreas appeared normal.
Spleen appeared normal.
Aorta appeared normal.
No free fluid in the peritoneal cavity.
No para aortic lymphadenopathy.
Adrenal glands appeared normal.

KUB

Cortex and collecting system of both kidneys appeared normal. No calculi seen.
Right Kidney measured 105 X 45 mm.
Left Kidney measured 106 X 47 mm.
Both ureters appeared normal. No dilatation seen.
Bladder appeared normal.

Pelvis

Normal appearing uterus with homogenous myometrial echoes.
Uterus measured 74 X 33 mm.
Endometrium measuring 7 mm.
Cavity echo appeared normal.
Right Ovary appeared normal.
Right Ovary measured 30 X 21 mm.
Left Ovary appeared normal.
Left Ovary measured 26 X 21 mm.
Both adnexae appeared normal.

Impression

NORMAL APPEARING LIVER, GALLBLADDER, COMMON DUCT, PANCREAS, SPLEEN, AORT. BOTH KIDNEYS, BLADDER, UTERUS, BOTH OVARIES.

Dr. ELAVARASAN, DMRD.,

ANNAII MEDICAL COLLEGE AND HOSPITAL

(SRI DEVI KARUMARIAMMAN EDUCATIONL TRUST)
Dr. G. Jayarama Nagar, Pennalur, Sriperumbudur, Chennai - 602 117.

USG - ABDOMEN

Patient's Name : Mrs. Thenmozhi Date : 23/12/15.

Age / Sex : 29/F. OP/IP No. 15/223022A

Ref. By Dr.

ABDOMEN

LIVER :
GB :
SPLEEN : (N)
PANCREAS

R KIDNEY : 9.2 X 3.6 cm
L. KIDNEY : 10.0 X 4.0cm (N)

BLADDER : (N)

~~PROSTATE :~~

RETRO PERITOWEUM : –

UTERUS : 7.4 X 4.9 X 5.6cm & It is Bulky.

ENDOMENTRIUM : 9.3mm

MYOMETRIUM (N)

R. OVARY : 3.6 X 2.6 X 2.5 cm (Vol: 13cc)
L. OVARY 3.6 X 2.0 X 2.9 cm (Vol: 11cc)

POD : –

Both ovaries are enlarged & cystic

IMPRESSION :

- Bulky Uterus.
- B/L Polycystic Ovary.
- Rest abdominal organs appears normal.

Sonologist

ANNAII MEDICAL COLLEGE AND HOSPITAL

(SRI DEVI KARUMARIAMMAN EDUCATIONL TRUST)
Dr. G. Jayarama Nagar, Pennalur, Sriperumbudur, Chennai - 602 117.

USG - PELVIS

Patient's Name : MRS. THENMOZHI Date : 18/4/16

Age / Sex : 30/F OP/ IP No. : 1604180287

Ref. By Dr.

PELVIS

BLADDER : (N)

UTERUS : Retroverted. 7.5x4.6x4.7 cm and Normal.

ENDOMETRIUM : 7.8 mm

MYOMETRIUM : (N)

R. OVARY : 3.0x1.4 cm

L. OVARY : 2.9x1.6 cm (N)

POD : —

IMPRESSION :

- Normal Study.

The Tamil Nadu Dr.M.G.R. Medical University

#69, Anna salai, Guindy, Chennai-600 032.

This certificate is awarded to

Dr./~~Mr.~~/~~Ms.~~ S. SHAGILA

for participating as ~~Resource Person~~ / Delegate in the Fourteenth Workshop on

"Research Methodology & Biostatistics"

for AYUSH Post Graduates & Researchers

Organised by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University from 5th to 9th May 2014.

Dr. N. KABILAN M.D. (Siddha) Reader, Dept. of Siddha	**Dr. JHANSI CHARLES,** M.D. Registrar	**Prof. Dr. D. SHANTHARAM,** M.D., D.Diab., Vice-Chancellor

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

CERTIFICATE OF BOTANICAL AUTHENTICITY

Certified that the following plant drugs used in the Siddha formulation **"Garpa vaayu ilagam"** (Internal) for the treatment of **Garpa vaayu** (Polycystic ovarian syndrome) taken up for Post Graduation Dissertation studies by **Dr.S.Shagila**, M.D.(S), II year, Department of Maruthuvam, 2015, are identified and authenticated through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology, Micromorphology and Taxonomical methods as

Operculina turpethum (Linn.) Silova Manso (Convolvulaceae), Root
Cassia senna Linn. (Caesalpiniaceae), Leaf and root
Cyperus rotundus Linn. (Cyperaceae), Rhizome
Zingiber officinale Rosc. (Zingiberaceae), Rhizome.
Piper nigrum Linn. (Piperaceae), Fruit
Piper longum Linn. (Piperaceae), Fruit and Root
Terminalia chebula Retz. (Combretaceae), Fruit
Terminalia bellirica (Gaertner) Roxb. (Combretaceae), Fruit
Phyllanthus emblica Linn. (Euphorbiaceae), Fruit
Carum copticum Benth. & Hook. f. (Apiaceae), Fruit
Picrorhiza kurroa Royle ex Benth. (Scrophulariaceae), Root
Embelia ribes Burm.f. (Myrsinaceae), Fruit
Aconitum heterophyllum Wall.ex Royle (Ranunculaceae), Root
Quercus infectoria Oliv. (Fagaceaae), Gall

Certificate No: NISMB1802015

Date: 24-08-2015

24/8/15
Authorized Signatory
Dr. D. ARAVIND, M.D.(s),M.Sc.,
Assistant Professor
Department of Medicinal Botany
National Institute of Siddha
Chennai - 600 047. INDIA

சித்த மருத்துவ மைய ஆராய்ச்சி நிலையம், அரும்பாக்கம், சென்னை - 600106
सिद्ध केन्द्रीय अनुसंधान संस्थान, अरुम्बाक्कम, चेन्नै - 600106
Siddha Central Research Institute
(Central Council for Research in Siddha, Ministry of AYUSH, Govt. of India)
Arumbakkam, Chennai – 600106
[Ph: 044-26214925, 26214809, Fax: 26214809, Email: crisiddha@gmail.com, Web: www.siddhacouncil.com]

29.12.2015

CERTIFICATE

Certified that the samples submitted for identification by Dr. S. Shagila, II year MD Student, Department of Maruthuvam, National Institute of Siddha, Sanatorium, Chennai-600 047 is identified as Indhuppu – Sodium chloride.

02/1/16
(R. Shakila)
Research Officer (Chemistry)

P. Elankeeni
(Dr. P. Elankeeni R.O(Ser.2))
for **(Dr. P.Sathiyarajeswaran)**
Assistant Director (Scientist 2)-I/c

சித்த மருத்துவ மைய அராய்ச்சி நிலையம், சென்னை — 600 106
सिद्ध केंद्रीय अनुसन्धान संस्थान, अण्णा सरकारी अस्पताल परिसर, अरुम्बाक्कम, चेन्नई - 600106

SIDDHA CENTRAL RESEACH INSTITUTE

(Central Council for Research in Siddha, Ministry of AYUSH, Govt. of India)
Anna Govt. Hospital Campus, Arumbakkam, Chennai – 600106
Phone: 044-2621 4925, Fax: 044-2621 4809
www.crisiddha.tn.nic.in, Email: crisiddha@gmail.com

15.06.2016

Name of the student: Dr.S. Shagila, III Year MD Student,
Department of Maruthuvam, National Institute of Siddha, Sanatorium, Chennai-600 047.

PHYSICO-CHEMICAL ANALYSIS OF GARPAVAYU ILAGAM

S.No	Parameter		Mean
1.	Loss on Drying at 105°C	:	11.77 %
2.	Total ash	:	3.33 %
3.	Water soluble Ash	:	1.27 %
4.	Acid insoluble Ash	:	0.48 %
5.	Water soluble extractives	:	52.17 %
6.	Alcohol soluble extractives	:	44.31 %
7.	pH	:	5.6
8.	Total solid	:	88.23%
9.	Fat content	:	12.18 %
10.	Reducing sugar	:	Nil
11.	Total Sugar	:	30.78 %
12.	HPTLC	:	Enclosed

(R. Shakila)
Research Officer (Chemistry)

15/6/16

(Dr. P. Sathiyarajeswaran)
Assistant Director (Scientist 2) I/c

Dr. P. SATHIYARAJESWARAN
...tor (Scientist-2) I/C
Siddha ...stitute (CCRS)
Arumbakkam, Chennai-600 106.